

1998

Medtronic, Inc. v. Lohr: Bad Medicine for Manufacturers of Unproven Medical Devices

Kenneth T. Sigman

Follow this and additional works at: <https://scholarship.law.edu/lawreview>

Recommended Citation

Kenneth T. Sigman, *Medtronic, Inc. v. Lohr: Bad Medicine for Manufacturers of Unproven Medical Devices*, 47 Cath. U. L. Rev. 721 (1998).

Available at: <https://scholarship.law.edu/lawreview/vol47/iss2/16>

This Notes is brought to you for free and open access by CUA Law Scholarship Repository. It has been accepted for inclusion in Catholic University Law Review by an authorized editor of CUA Law Scholarship Repository. For more information, please contact edinger@law.edu.

MEDTRONIC, INC. V. LOHR: BAD MEDICINE FOR MANUFACTURERS OF UNPROVEN MEDICAL DEVICES

Kenneth T. Sigman⁺

As a result of the Supremacy Clause¹ of the United States Constitution, federal law may preempt state law under the Preemption Doctrine.² Federal law may trump state law either when an actual conflict exists between federal and state law, or when Congress, acting within the scope of its plenary powers, prohibits concurrent state regulation.³ Courts will

⁺ J.D. candidate, May 1998, The Catholic University of America, Columbus School of Law.

1. See U.S. CONST. art. VI, cl. 2. The Supremacy Clause provides: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land" *Id.* Alexander Hamilton explained the basis for the Supremacy Clause as follows:

If a number of political societies enter into a larger political society, the laws which the latter may enact, pursuant to the powers intrusted to it by its constitution, must necessarily be supreme over those societies and the individuals of whom they are composed. It would otherwise be a mere treaty, dependent on the good faith of the parties, and not a government, which is only another word for POLITICAL POWER AND SUPREMACY.

THE FEDERALIST NO. 33, at 204 (Alexander Hamilton) (Clinton Rossiter ed., 1961).

James Madison explained the consequences of enacting a national constitution with a saving clause granting the state constitutions supremacy over the national constitution. See THE FEDERALIST NO. 44, at 286 (James Madison). First, because each of the state constitutions created absolute sovereignty in the state legislatures, except where the Articles of Confederation provided otherwise, the powers of the national government would be annulled by the state constitutions to the extent that the national powers exceeded those enumerated under the Articles of Confederation. See *id.* The result would be a new Congress as "impotent" as its predecessor. See *id.* Additionally, because the state constitutions differ from each other, a law passed by the national legislature—equally important to every state—might be unconstitutional in some states and valid in others. See *id.* at 287.

2. See 2 RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE § 12.1, at 62-63 (2d ed. 1992); see also *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 108 (1992); *New York Cent. R.R. Co. v. Winfield*, 244 U.S. 147, 148 (1917). But cf. Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767, 773-74, 776-77 (1994) (arguing that the federal preemption power is not derived from the Supremacy Clause because the Clause is a dispute resolution provision).

3. See 2 ROTUNDA & NOWAK, *supra* note 2, § 12.1, at 63. The underlying rationale behind the Preemption Doctrine is "to avoid conflicting regulation of conduct" by two rulemaking bodies. *Id.* at 72. For this reason, the doctrine is applied not only to legislative enactments, but also to regulations emanating from administrative bodies and court decisions. See 21 C.F.R. § 808.1(b) (1997) (defining the preemptive scope of a federal statute).

find preemption in two circumstances.⁴ First, express preemption arises when Congress includes a provision in a statute that explicitly prohibits state regulation of a certain subject matter.⁵ When a statute includes an express preemption clause, the language of that clause governs the preemptive scope of the statute.⁶ Second, courts may imply congressional intent to preempt state tort law in limited circumstances.⁷

to include state law, "whether established by statute, ordinance, regulation, or court decision"); *cf.* *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) (stating that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief").

4. See JOHN E. NOWAK & RONALD D. ROTUNDA, *CONSTITUTIONAL LAW* § 9.1, at 319-20 (5th ed. 1995) (describing the analytical framework of federal legislative preemption).

5. See, e.g., 7 U.S.C. § 136v(b) (1994) (prohibiting additional or different state labeling requirements for chemicals with a federally approved label); 21 U.S.C. § 360k(a) (1994) (prohibiting state regulations of medical devices that is different from or in addition to federal regulation); 21 U.S.C. § 678 (1994) (prohibiting state "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than, [federal requirements]"); 49 U.S.C. § 20106 (1994) (prohibiting state regulation of railroad safety in situations where the Secretary of Transportation already has prescribed such a regulation).

6. See *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) ("If [a] statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent."); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) ("Congress's enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.").

Disagreement exists as to whether courts, when faced with an express preemption clause, should examine the substantive provisions of a statute to find implied preemption. In *Cipollone*, the majority refused to apply an implied preemption analysis because the Court was faced with an express preemption clause. See 505 U.S. at 517 (stating that where Congress has enacted a provision defining the preemptive reach of a statute, matters beyond that reach are not preempted (citing *California Federal Savings & Loan Ass'n v. Guerra*, 479 U.S. 272, 282 (1987) (opinion of Marshall, J.)). In dissent, Justice Scalia argued that courts still must apply an implied conflict preemption analysis in the face of an express preemption clause. See *id.* at 547 (Scalia, J., concurring in part and dissenting in part). Justice Scalia argued that if a court refuses to apply an implied conflict preemption analysis when faced with an express preemption clause, that court will frustrate the purpose of the clause. See *id.* By way of example, Justice Scalia explained that if a federal law included a clause prohibiting any state-imposed workplace safety laws contradicting federal safety laws, the courts could not find preemption of a state law that in fact imposes a standard on workplace safety if that law had been enacted as a consumer protection law. See *id.* Justice Scalia agreed with the majority that the courts should not apply an implied field preemption analysis when faced with an express preemption clause. See *id.* Justice Scalia reasoned that an express preemption clause contradicts any implication that Congress intended to occupy a field broader than that defined in the clause. See *id.* See generally *infra* note 7 (discussing conflict preemption).

7. See Philip H. Corboy & Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption*, 15 AM. J. TRIAL ADVOC. 435, 446 (1992). Courts may infer congressional intent to preempt state law in three situations. See *id.* at 446-48. First, implied "field preemption" can result when Congress enacts comprehensive legislation governing every aspect of a certain subject matter. See *id.* at 446; see

The principles of federalism and state sovereignty dictate that courts construe statutory language with a presumption against preemption.⁸ The presumption is particularly strong when the subject matter of a federal statute relates to health or safety,⁹ areas that traditionally have been left to the states.¹⁰ Accordingly, unless Congress expresses a clear and manifest purpose to preempt state tort law, courts will not find preemption.¹¹

also *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983) (reasoning that states could not regulate safety aspects of nuclear power plants because "Congress' intent to supersede state law altogether may be found from a 'scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it . . .'" (quoting *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982))). Second, implied "conflict preemption" results when a direct conflict arises between state and federal law, so that compliance with both laws is a "physical impossibility." See *Corboy & Smith, supra*, at 447; see also *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984) (stating that where "Congress has not entirely displaced state regulation over the matter in question, state law is still pre-empted to the extent it actually conflicts with federal law . . ."). But see *Gardbaum, supra* note 2, at 775-76. Professor Gardbaum explains that all preemption scenarios may be characterized as conflict cases. See *id.* at 775. He explains that in both "express" and "implied" preemption scenarios, there is an actual conflict "between Congress's . . . intent that there should be no state regulation" of a given field and state regulatory actions in that field. See *id.* at 775-76. The third type of implied preemption occurs where a state law "stands as an obstacle" to federal law. See *Corboy & Smith, supra*, at 448. This Note does not discuss "stands as an obstacle" preemption.

8. See *Corboy & Smith, supra* note 7, at 448-49. The authors argue that courts should be reluctant to find preemption of state laws because states are incapable of correcting improper decisions while the federal government is free to correct improper judicial decisions through congressional legislation. See *id.* at 449 (citing *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 643 (1973) (Rehnquist, J., dissenting)).

9. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) ("Congress legislated here in a field which the States have traditionally occupied. So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." (citations omitted)). But cf. *Cipollone*, 505 U.S. at 545 (Scalia, J., dissenting in part). Justice Scalia argued that courts should not give express preemption clauses the narrowest possible construction. See *id.* Rather, Justice Scalia argued, when Congress has included an express preemption clause in a statute, the assumption that the historic police powers of the states are not to be superceded dissolves, and courts should apply ordinary principles of statutory construction. See *id.* at 545-46 (citing *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992)).

10. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2250 (1996); *Corboy & Smith, supra* note 7, at 451.

11. See *Medtronic*, 116 S. Ct. at 2250; cf. *New York State Dep't of Soc. Serv. v. Dublino*, 413 U.S. 405, 413 (1973) ("The exercise of federal supremacy is not lightly to be presumed." (quoting *Schwartz v. Texas*, 344 U.S. 199, 203 (1952))); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) ("The principle to be derived from our decisions is that federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmis-

The Medical Device Amendments of 1976 (MDA)¹² exemplify federal preemptive legislation in an area traditionally regulated by the states.¹³ Congress enacted the MDA following a rapid increase in reliance on medical devices and a corresponding increase in the number of injuries caused by device failure.¹⁴ Prior to these 1976 amendments, the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA)¹⁵ empowered the United States Food and Drug Administration (FDA) to take regulatory action regarding a medical device after the device appeared on the market and failed.¹⁶ In an effort to curb injuries, Congress enacted the MDA to ensure the safety of medical devices prior to entering the market¹⁷ and to prevent variant state regulation from impeding the development of new devices.¹⁸

takably so ordained.”).

12. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.) (amending the Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938)).

13. See Bianca I. Truitt, *Injured Consumers and the FDA: Should Federal Preemption Protect Medical Device Manufacturers Under a Quasi-Governmental Immunity?*, 15 J. LEGAL MED. 155, 157 (1994) (noting that one of the goals of the MDA was to protect the public).

14. See S. REP. NO. 94-33, at 6-7 (1975) (noting that as of 1970, scientific literature recorded more than 10,000 serious injuries associated with medical devices, including 731 deaths). In particular, the numerous deaths and miscarriages caused by the A.H. Robins Company's Dalkon Shield intrauterine device prompted enactment of the MDA. See Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 911-12 & n.84 (1994).

15. Pub. L. No. 675-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-395 (1994)). During the 1930s, concern over unsafe medical devices led reformers to pressure for congressional legislation empowering the Food and Drug Administration to protect the public against such devices. See S. REP. NO. 94-33, at 2. During the era in which the FDCA was enacted, most legitimate medical devices were simple enough that doctors could determine easily whether a device was functioning properly. See *id.* at 2-3. Legitimate devices available at that time included “surgical instruments, trusses, prosthetic devices, ultraviolet lights, contraceptives, and orthopedic shoes.” *Id.* at 2. With regard to legitimate devices, the FDCA aimed to promote truth in labeling. See *id.* at 3. Early FDA activity also included attempts to combat obviously dangerous devices such as lead nipple shields. See *id.*

16. See Truitt, *supra* note 13, at 156-57.

17. See Robert Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 511-12 (1988).

18. See Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L. J. 1, 5-6 (1996). The first step leading to the MDA was the Department of Health, Education, and Welfare's sponsorship of the “Study Group on Medical Devices,” or Cooper Committee, formed in 1969. See James S. Benson et al., *The FDA's Regulation of Medical Devices: A Decade of Change*, 43 FOOD DRUG COSM. L.J. 495, 495 (1988). The Cooper Committee's purpose was to recommend a strategy for developing standards for medical devices. See *id.* The Cooper Committee concluded that federal regulation of medical devices was preferable to private or state

To achieve the dual goals of protecting consumers and ensuring the availability of new devices, Congress categorized medical devices according to the risk posed to consumers and authorized the FDA to promulgate corresponding regulatory controls.¹⁹ The FDA categorizes devices that play a significant role in sustaining human life or preventing impairment of human health as Class III devices and must, with one significant exception,²⁰ receive “premarket approval.”²¹ To obtain premarket approval, the manufacturer of a new device must demonstrate, through clinical testing, that the device is safe and effective.²²

regulation because of funding, enforcement, and cohesiveness considerations. *See id.* at 496.

19. *See* 21 U.S.C. § 360c (1994) (designating three classes of devices and authorizing the FDA to promulgate appropriate regulations). Class I devices are devices that: (1) the manufacturer does not purport to be for use in sustaining human life or substantially preventing impairment of health; and (2) do not present an unreasonable risk of injury. *See id.* § 360c(a)(1)(A)(ii). The EPA subjects Class I devices only to the general controls authorized by the MDA. *See id.* § 360c(a)(1)(A). Class II devices are devices for which the general controls are insufficient to ensure safety and effectiveness, but sufficient information is available to impose performance standards to ensure the safety of the device. *See id.* § 360c(a)(1)(B); *see also* Benson et al., *supra* note 18, at 495 (discussing the development of standards and regulations under the MDA).

20. *See infra* notes 23-24 and accompanying text (discussing an exception for new devices that are substantially equivalent to devices on the market prior to the enactment of the MDA). Another exception, the Investigational Device Exemption (IDE), promotes the development of innovative medical devices by exempting them from the premarket approval process. *See* 21 U.S.C. § 360j(g) (1994). Regulations promulgated pursuant to § 360j(g) establish procedures for device manufacturers to obtain an IDE. Manufacturers seeking an IDE must submit an application to the FDA containing “[a] complete report of prior investigations of the device,” an “investigational plan,” and detailed information on the “manufacture, processing, packing, storage, and . . . installation of the device.” 21 C.F.R. § 812.20(b)(1)-(3) (1997).

The investigational plan must include “the objectives and duration of the investigation;” a description of the methodology to be used in the investigation; a written analysis of protocol demonstrating the scientific soundness of the investigation; an analysis of the risks to subjects of the investigation; a description of each major “component, ingredient, property, and principle of operation . . . and . . . anticipated change[s] in the device”; monitoring procedures; labeling for the device; and informed consent forms. *Id.* § 812.25(a)-(g). The report of prior investigations must include evidence of all prior testing, a bibliography of all publications, and a summary of unpublished information “relevant to an evaluation of the safety or effectiveness of the device.” *Id.* § 812.27. Based on the information included in the application, the FDA will grant an IDE unless it determines that:

[t]here is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective.

Id. § 812.30(b)(4).

21. 21 U.S.C. § 360c(a)(1)(C) (1994).

22. *See id.* § 360c(a)(3)(A).

The significant exception to the premarket approval requirement allows new Class III devices that are "substantially equivalent" to a device that was available prior to the enactment of the MDA to enter the market through the "premarket notification" process.²³ The premarket notification process, the purpose of which is to avoid creating a greater regulatory burden for manufacturers of new devices, does not require the manufacturer to demonstrate that the "substantially equivalent" device is safe or effective.²⁴

In addition to the "substantially equivalent" exception to the premarket approval process, Congress included a preemption clause²⁵ in the MDA to further encourage the development of new medical devices by ensuring uniform regulation.²⁶ In the Act's preemption clause, 21 U.S.C. § 360k, Congress prohibited states from creating or enforcing any requirements regarding the safety or effectiveness of a MDA-regulated device that is different from or in addition to an existing FDA regulation.²⁷

23. See *id.* § 360e(b)(1).

24. See Benson et al., *supra* note 18, at 500 (noting that the MDA is "[d]esigned to provide equity among manufacturers"); Adler, *supra* note 17, at 516 ("If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective."). The premarket notification process requires an average of 20 hours of FDA review per device, while the premarket approval process requires an average of 1200 hours per device. See Benson et al., *supra* note 18, at 500. Contrary to congressional intent, the vast majority of Class III devices come to market via the premarket notification process. See Adler, *supra* note 17, at 515-16. In 1990, for example, 80% of new Class III devices were entering the market through the premarket notification process. See H.R. REP. NO. 101-808, at 14 (1990).

Medical device manufacturers seeking to market their product through the premarket notification process are required to submit a "Premarket Notification Summary" to the FDA. See 21 C.F.R. § 807.92(a) (1997). The summary must contain the following: (1) the name of the party seeking to market a new device, *see id.* § 807.92(a)(1); (2) the name of the device legally marketed before May 28, 1976 (the effective date of the MDA) to which the new device is equivalent, *see id.* § 807.92(a)(2); (3) the name of the new device, *see id.* § 807.92(a)(3); (4) a description of the new device such as would be found in the labeling or promotional materials for the device, including how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics, such as the design, materials, and physical properties, *see id.* § 807.92(a)(4); (5) a description of the diseases or conditions the device cures, treats, diagnoses, or prevents, *see id.* § 807.92(a)(5); and (6) an explanation of the significant differences between the new device and the pre-1976 device, *see id.* § 807.92(a)(6).

25. See 21 U.S.C. § 360k(a) (1994).

26. See Truitt, *supra* note 13, at 163 (noting that the uniformity of regulation which follows from the preemption of state requirements minimizes the medical device industry's compliance costs).

27. See 21 U.S.C. § 360k(a) (1994). This section prohibits any state requirement: "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." *Id.*

Until 1992, when the Supreme Court held that the preemption clause of a cigarette labeling statute barred certain tort claims against cigarette companies,²⁸ medical device manufacturers did not often assert a preemption defense.²⁹ Following this decision, medical device manufacturers whose products allegedly caused injury to consumers began to assert that the MDA preempted a victim's state tort claims because the claims, if successful, would constitute state-imposed "requirements."³⁰ The federal courts met the manufacturers' preemption arguments with varying degrees of acceptance.³¹ In 1996, the United States Supreme Court sought to clarify the preemptive scope of the MDA when it granted certiorari in *Medtronic, Inc. v. Lohr*.³²

Medtronic arose as the result of a failed pacemaker lead. In 1987, doctors implanted a Medtronic pacemaker in Lora Lohr.³³ Medtronic equipped the pacemaker with its Model 4011 pacemaker lead,³⁴ a Class III medical device that came to market through the premarket notification process as a device "substantially equivalent" to a pre-1976 device.³⁵ In 1990, Ms. Lohr's pacemaker failed, necessitating emergency surgery to save her life.³⁶ According to Ms. Lohr's physician, a defect in the 4011 lead likely caused the pacemaker's failure.³⁷

Claiming the manufacturer was liable based on both strict liability and negligence theories, Ms. Lohr sued Medtronic in Florida state court.³⁸

28. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530-31 (1992) (holding that state damage awards constitute requirements and are subject to preemption); see also *infra* Part I.B. (discussing *Cipollone*).

29. See *Adler & Mann, supra* note 14, at 916 (noting that prior to *Cipollone*, courts viewed compliance with federal government standards as a "weak shield" for defendants accused of violating state laws).

30. See, e.g., *English v. Mentor Corp.*, 67 F.3d 477, 480 (3d Cir. 1995) (penile implant); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995) (pacemaker), *aff'd in part and rev'd in part*, 116 S. Ct. 2240 (1996); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir. 1992) (intraocular lens).

31. See, eg., cases cited *infra* notes 115 and 117. See generally *Adler & Mann, supra* note 14, at 916-23 (discussing the variant preemptive effect given to the MDA by the courts).

32. 116 S. Ct. 2240 (1996).

33. See *id.* at 2248.

34. See *Lohr*, 56 F.3d at 1340. A pacemaker lead is the wire that carries electrical impulses from the pacemaker to the patient's heart tissues. See *id.*

35. See *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2248 (1996).

36. See *id.*

37. See *id.*

38. See *id.* The negligence claim alleged that Medtronic breached its "duty to use reasonable care in the design, manufacture, assembly, and sale of the . . . pacemaker." *Id.* Specifically, Lohr alleged that Medtronic used defective materials for the 4011 lead and failed to warn or instruct the patient or her physician of the device's tendency to fail, not-

Medtronic removed the case to the United States District Court for the Middle District of Florida and moved for summary judgment on both counts, arguing that 21 U.S.C. § 360k³⁹ preempted such claims.⁴⁰ The district court originally denied Medtronic's motion for summary judgment; but following a ruling by the Eleventh Circuit Court of Appeals, the district court reversed the earlier denial and dismissed Ms. Lohr's entire complaint.⁴¹ The United States Court of Appeals for the Eleventh Circuit reversed in part and remanded in part.⁴² In *Lohr v. Medtronic, Inc.*, the court of appeals held that § 360k did not preempt Ms. Lohr's negligent design claims because the premarket notification process did not impose federal requirements on the design of the 4011 lead.⁴³ However, the court of appeals, held that the section did preempt Ms. Lohr's negligent manufacturing and labeling claims because of general manufacturing and labeling requirements applicable to the pacemaker lead through the MDA.⁴⁴

withstanding Medtronic's awareness of previous failures. *See id.* The strict liability claim alleged that the device was defective and posed an unreasonable hazard to users. *See id.* Lohr's additional breach of warranty claim was dismissed for failure to state a claim under Florida law. *See id.*

39. *See supra* note 27 and accompanying text (discussing and quoting the provisions of § 360k).

40. *See Medtronic*, 116 S. Ct. at 2248.

41. *See id.* at 2249. The Eleventh Circuit ruled that § 360k preempted some, but not all common law claims against medical device manufacturers. *See Duncan v. Iolab Corp.*, 12 F.3d 194, 195 (11th Cir. 1994) (*per curiam*).

42. *See Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1352 (11th Cir. 1995), *aff'd in part and rev'd in part*, 116 S. Ct. 2240 (1996); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1334 (7th Cir. 1992) (intraocular lens).

43. *See Lohr*, 56 F.3d. at 1347-49. Central to the Eleventh Circuit's holding that Lohr's negligent design claims survived preemption was the determination that premarket approval alone neither represented a finding of safety or effectiveness nor imposed specific federal requirements on a device. *See id.* at 1348.

44. *See id.* at 1350. Finding the preemptive scope of § 360k unclear, the court turned to the FDA regulation interpreting the section. *See id.* at 1343 (citing *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843-44 (1984)). In *Chevron*, the Supreme Court held that when a statute is silent or ambiguous with respect to a specific issue, an agency's construction of that statute is preferable to a judicial construction. *See* 467 U.S. at 843; *see also infra* (discussing *Chevron*). The FDA regulation at issue provided that state requirements be preempted only when there are specific federal regulations applicable to a device. *See* 21 C.F.R. § 808.1(d) (1997). The Eleventh Circuit understood this provision to mandate that a specific federal requirement be applicable to a device, rather than requiring a device-specific federal requirement in order to trigger preemption. *See Lohr*, 56 F.3d at 1345. Accordingly, the court reasoned that the good manufacturing practices applicable to the 4011 pacemaker lead through the MDA, while not device-specific, were requirements specific to the manufacturing of the device. *See id.* at 1350. Similarly, the court found that the labeling requirements applicable to the device through the MDA were "quite specific about what standards a manufacturer must follow when designing the packaging and labeling for its product." *Id.* at 1351.

A plurality of the Supreme Court held that § 360k did not preempt any of Ms. Lohr's claims.⁴⁵ First, the plurality found that Congress did not intend for the MDA to preempt all common law claims against medical device manufacturers.⁴⁶ Next, the plurality examined Ms. Lohr's claims and found that each of them survived preemption because the claims, if successful, would not have the effect of imposing requirements that were different from or in addition to the federal regulations applicable specifically to the safety of the 4011 lead.⁴⁷ Finally, the plurality declined to decide whether common law duties ever could impose "requirements" on a device subject to preemption under § 360k.⁴⁸ Justice Breyer concurred, but emphasized that successful state common law claims do impose "requirements" and that the MDA would preempt claims alleging that federally mandated conduct is negligent.⁴⁹

The dissent argued that the MDA did preempt Ms. Lohr's negligent manufacturing and failure to warn claims.⁵⁰ First, the dissent echoed Jus-

Chevron involved an Environmental Protection Agency (EPA) regulation promulgated under the Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685 (1977) (Amendments). See *Chevron*, 467 U.S. at 839. The Amendments required states that had not met EPA air quality standards to devise a permit system to regulate major "stationary sources" of pollution. See *id.* at 840. The EPA regulation at issue defined stationary sources as all pollution-emitting devices within a single industrial grouping. See 40 C.F.R. §§ 51.18(j)(1)(i)-(ii) (1983). As a result, industrial plants with multiple pollution sources could modify one device without meeting permit requirements provided the total emissions of the plant did not increase. See *Chevron*, 467 U.S. at 840.

When reviewing an agency's construction of a statute, the Court said that courts must first look to whether Congress has directly addressed the question at issue. See *id.* at 842. If Congress has directly addressed the question, the reviewing court and agency must defer to the intent of Congress. See *id.* at 842-43. If Congress has not directly addressed the question, the role of the court is to determine whether the agency's construction was "based on a permissible construction of the statute." *Id.* at 843. See generally Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2091-92 (1990) (noting that *Chevron* does not indicate the degree of ambiguity a statute must have to warrant judicial deference to an agency interpretation and suggesting that the mere existence of two reasonable interpretations is insufficient to trigger such deference). Examining the statutory language, the Court found that the only congressional intent discernible from the ambiguous definition of "stationary sources" was an intent to enlarge the EPA's discretion to define the term. See *Chevron*, 467 U.S. at 862; see also Sunstein, *supra*, at 2086 (noting that the resolution of statutory ambiguities may involve questions of policy and reiterating that agencies are better suited than courts to make such policy decisions). Following similar reasoning, the Court found the EPA's construction of the amended Act permissible. See *Chevron*, 467 U.S. at 866.

45. See *Medtronic*, 116 S. Ct. at 2258.

46. See *id.* at 2251 (plurality opinion).

47. See *id.* at 2253-58.

48. See *id.* at 2258-59 (plurality opinion).

49. See *id.* at 2259 (Breyer, J., concurring in part and concurring in the judgment).

50. See *id.* at 2264 (O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, J.J., concurring in part and dissenting in part).

tice Breyer's assertion that common law duties constitute requirements within the meaning of § 360k.⁵¹ Next, the dissent maintained that the language of § 360k did not warrant the plurality's requirement that a device specific federal regulation be applicable to the device to trigger preemption.⁵² Consequently, the dissent argued that federal manufacturing and labeling requirements applicable to all medical devices preempted Ms. Lohr's negligent manufacturing and failure to warn claims.⁵³

This Note first traces the Supreme Court's approach to federal preemption of state tort claims from 1984 to 1992, explaining the evolution from the Court's refusal to find preemption of state tort claims absent an exclusive federal remedy, to its finding that an award of damages resulting from a state tort claim was a form of direct state regulation subject to preemption. This Note next examines the lower courts' variant interpretations of the preemptive scope of the MDA with regard to state tort claims. This Note then discusses the plurality, concurring, and dissenting opinions in *Medtronic*. Finally, this Note argues that while the *Medtronic* plurality correctly decided that the MDA did not preempt Ms. Lohr's claims, the plurality failed to go far enough to prevent courts from finding preemption of tort claims in situations that Congress never anticipated.

I. PREEMPTION AND STATE TORT CLAIMS IN THE SUPREME COURT

A. *Silkwood v. Kerr-McGee Corp.*: *No Preemption Without an Exclusive Federal Remedy for Victims of Tortious Conduct*

Prior to 1984, the Supreme Court had not considered whether federal regulations that govern an actor's conduct could preempt state tort claims when the regulations did not create an exclusive federal remedy.⁵⁴ When faced with the issue, the Court found tort awards to be an insufficiently direct form of regulation to warrant preemption and demonstrated an unwillingness to leave injured plaintiffs without any remedy simply because federal law regulated the defendant's conduct.⁵⁵

*Silkwood v. Kerr-McGee*⁵⁶ involved an award of actual and punitive damages under state common law tort principles for injuries that oc-

51. See *id.* at 2262.

52. See *id.* at 2263.

53. See *id.* at 2264.

54. See Lars Noah, *Reconceptualizing Federal Preemption of Tort Claims As the Government Standards Defense*, 37 WM. & MARY L. REV. 903, 907-08 (1996).

55. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 250-51 (1984).

56. 464 U.S. 238 (1984).

curred in a federally licensed nuclear facility operated by appellee Kerr-McGee Corporation.⁵⁷ Relying on the Court's prior holding that the Atomic Energy Act⁵⁸ (AEA) preempted all state regulation of safety aspects of nuclear facilities,⁵⁹ Kerr-McGee asserted that the AEA should preempt the state damage award because it constituted a form of state regulation in a prohibited field.⁶⁰

Karen Silkwood, a laboratory analyst at a Kerr-McGee nuclear fuel plant, became contaminated by plutonium radiation.⁶¹ Soon after her contamination, Ms. Silkwood died as a result of an unrelated automobile accident, and her father filed suit on behalf of her estate to recover for her injuries caused by the contamination.⁶² A jury awarded the Silkwood estate actual and punitive damages.⁶³ The Tenth Circuit reversed the jury's punitive damages award, holding that the AEA preempted the award.⁶⁴

Upon review, the Supreme Court focused on Congress's failure to address preemption of state tort claims in the AEA and on the absence of federal remedies for injuries incurred in a nuclear facility.⁶⁵ The Court understood Congress's failure to mention that it intended the AEA to extinguish all nuclear accident victims' state law claims as an indication that Congress did not intend to preclude the availability of such remedies.⁶⁶ The Court then examined the attention given to tort liability in an

57. *See id.* at 243-45.

58. 42 U.S.C. §§ 2011-2284 (1994).

59. *See Silkwood*, 464 U.S. at 240-41 (citing *Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 211-13 (1983)). In *Pacific Gas & State Electric*, the Court implied congressional intent to preempt state law. *See* 461 U.S. 190, 212-13. The Court found that Congress intended for the federal government to occupy completely the field of nuclear safety. *See id.* at 212; *see also supra* note 7 and accompanying text (discussing the variant forms of implied preemption theory).

60. *See Silkwood*, 464 U.S. at 249. Kerr-McGee argued that a state-authorized damages award would deter and punish improper conduct related to nuclear safety and, therefore, the AEA preempted such an award. *See id.*

61. *See id.* at 241.

62. *See id.* at 242-43.

63. *See id.* at 245. The jury awarded the Silkwood estate \$505,000 in actual damages and \$10 million in punitive damages. *See id.*

64. *See Silkwood v. Kerr-McGee Corp.*, 667 F.2d 908, 923 (10th Cir. 1981), *rev'd*, 464 U.S. 238 (1984). The Tenth Circuit also reversed the majority of the actual damages awarded, holding that the state Workers' Compensation Act provided the estate with its sole remedy. *See id.* at 920.

65. *See Silkwood*, 464 U.S. at 249.

66. *See id.* at 251 (citing *United Constr. Workers v. Laburnum Constr. Corp.*, 347 U.S. 656, 663-64 (1954)).

amendment to the AEA, the Price-Anderson Act,⁶⁷ which limited the amount of damages that could be awarded in the event of a nuclear accident.⁶⁸ While the Price-Anderson Act did not actually apply to the facility in question,⁶⁹ the Court found the Act indicative of Congress's lack of intent for the AEA to preempt tort claims.⁷⁰

The Court also addressed Kerr-McGee's attempt to distinguish actual and punitive damages and Kerr-McGee's assertion that Congress intended to preempt at least the latter, if not the former.⁷¹ The Court rejected the corporation's argument.⁷² The Court explained that punitive damages were a traditional part of state damage awards.⁷³ The Court determined that Congress did not intend the AEA to preempt traditional state tort principles unless it did so expressly,⁷⁴ and the Court found no indication of such an intent in the legislative history or regulations.⁷⁵ In an amicus curiae brief, the United States argued that the AEA should preempt punitive damage awards because the AEA authorizes the Nuclear Regulatory Commission to impose civil penalties for violations of federal standards.⁷⁶ The Court rejected this argument, reasoning that

67. Pub. L. No. 85-256, 71 Stat. 576 (1957) (codified as amended in scattered sections of 42 U.S.C.).

68. *See Silkwood*, 464 U.S. at 251.

69. *See id.* The Act applied only to facilities that were required to maintain financial protection and were therefore eligible for federal indemnification. *See id.* at 251 n.12. Plutonium processing plants such as the plant in *Silkwood* were not required to maintain financial protection until 1977. *See id.* at 252 n.12 (citing 42 Fed. Reg. 46 (1977)).

70. *See id.* at 251-52. The Court examined the Joint Committee Report on the original Price-Anderson Act and found that Congress intended for the Act to interfere with state tort law only when the damage awards of state courts exceeded the federal limitation on liability. *See id.* at 252 (quoting S. REP. NO. 85-296, at 9 (1957)).

71. *See id.* at 255.

72. *See id.*

73. *See id.*

74. *See id.*

75. *See id.* The Court placed the burden of proving that Congress intended to preclude punitive awards on Kerr-McGee. *See id.* (citing *International Bhd. Elec. Workers v. Foust*, 442 U.S. 42, 53 (1979) (Blackmun, J., concurring in the result)). Kerr-McGee failed to point to any evidence either in the legislative history or in the regulations indicating that punitive damages should be precluded. *See id.* Rather, the Court found that the regulations implementing the Price-Anderson Act indicated that punitive damages could still be awarded under state law. *See id.* The Nuclear Regulatory Commission published its nuclear energy liability policies and indemnity agreements where it recited the waivers being exercised by the facility operators. *See id.* at 255 n.17. The publication provided that the waivers did not apply to punitive damages. *See id.* (quoting 10 C.F.R. § 140.91, Appendix A, para. 2(c), at 801 (1983)). The Court concluded that, had there been any existing federal law prohibiting state punitive damages awards, the provision stating that the waivers do not apply to such awards would not have been necessary. *See id.*

76. *See id.* at 257.

Kerr-McGee could be required to pay federal fines as well as state-imposed punitive damage awards arising out of the same incident.⁷⁷ Next, the Court addressed Kerr-McGee's argument that allowing states to award punitive damages would frustrate the express goal of the AEA, to promote atomic energy.⁷⁸ The Court responded by noting that the Act was primarily intended to protect the health and safety of the public from the dangers of atomic energy production, and that the goal of protecting health and safety encompassed the goal of promoting atomic energy.⁷⁹ For this reason, the Court held that punitive awards did not hinder the goal of the Act.⁸⁰

In dissent, Justice Blackmun argued that courts should bifurcate the issues of punitive and compensatory damages because punitive damages serve to regulate safety while compensatory damages serve to compensate victims.⁸¹ Justice Blackmun reasoned that, because the Court's holding in *Pacific Gas & Electric*⁸² dictated that state regulation of nuclear safety matters was prohibited, the Court should allow only the compensatory damages.⁸³

77. See *id.*

78. See *id.*

79. See *id.* (citing 42 U.S.C. § 2013(d) (1994)).

80. See *id.*

81. See *id.* at 263 (Blackmun, J., dissenting in part).

82. 461 U.S. 190 (1983).

83. See *Silkwood*, 464 U.S. at 263-64 (Blackmun, J., dissenting in part). In *English v. General Elec. Co.*, the Court again rejected a preemption defense where a state tort claim arose out of incidents occurring at a nuclear facility. See 496 U.S. 72, 90 (1990). Petitioner, Vera English, filed a state law claim for intentional infliction of emotional distress because of retaliatory treatment she received from her employer, General Electric, following her report of safety violations to federal authorities. See *id.* at 74-77. The Court began its discussion of the case with a field preemption analysis and held that the state damage award at issue would not have a sufficiently direct or substantial effect on safety matters at nuclear facilities to fall within the preempted field. See *id.* at 85. The Court noted the incongruity that would result if it found that tort awards based on retaliation against "whistle-blowers" were preempted when the Court previously held in *Silkwood* that the AEA did not preempt tort awards based on actual safety violations. See *id.* at 86.

The Court next addressed the issue of whether an actual conflict with federal law would result if it allowed the state damage award to stand. See *id.* at 87. Contrary to the situation in *Silkwood*, in *English*, the AEA created a federal remedy for victims of retaliatory actions resulting from reports of safety violations. See *id.* The Secretary of Labor is authorized to compensate the victims of employer retaliation where the employer is motivated by reports of safety violations. See 42 U.S.C. § 5851(b)(2)(13) (1982). The Court rejected General Electric's contention that the existence of a federal remedy caused an inevitable conflict with state tort awards. See *English*, 496 U.S. at 88. The Court found that state causes of action need not be preempted solely because the state imposes liability greater than that which the federal law imposes. See *id.* at 89 (citing *California v. ARC Am. Corp.*, 490 U.S. 93, 105 (1989)).

B. Cipollone v. Liggett Group, Inc.: State Tort Awards Constitute Regulations Subject to Preemption

In *Cipollone v. Liggett Group, Inc.*,⁸⁴ the Supreme Court, in a plurality opinion authored by Justice Stevens, sharply curtailed its inclination previously demonstrated in *Silkwood* to preserve state law claims in the face of expansive federal regulation.⁸⁵ The Court's new willingness to find preemption of state tort claims resulted from its belief that tort damage awards were a form of direct state regulation.⁸⁶

In *Cipollone*, the Court addressed the issue of whether either of two federal statutes regulating the packaging and advertising of cigarettes preempted common law tort claims against a cigarette manufacturer.⁸⁷ Based on the reasoning that Congress's inclusion of an express preemption clause prevented the Court from conducting an implied preemption analysis, the Court focused solely on the language of the preemption clause in each statute.⁸⁸

The preemption clause in the first federal statute prohibited the states from requiring cigarette manufacturers to include any information regarding the health implications of smoking in any cigarette advertisements or packages when the advertising or packaging already complied with federal law.⁸⁹ The Court found that the preemptive language of this first statute did no more than prohibit states from mandating that ciga-

84. 505 U.S. 504 (1992) (plurality opinion).

85. See Noah, *supra* note 54, at 913 (noting the *Cipollone* Court's departure from the reasoning of *Silkwood*).

86. See *id.* at 925 (discussing the *Cipollone* Court's reasoning as to the regulatory effect of tort damages awards).

87. See *Cipollone*, 505 U.S. at 508. Compare Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 5(a), 79 Stat. 282, 283 (1965) (codified as amended at 15 U.S.C. § 1334 (1994)) (requiring a warning on cigarette packages that "Smoking *May* Be Hazardous to Your Health" (emphasis added)), with Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 5, 84 Stat. 87, 88 (1970) (codified as amended at 15 U.S.C. § 1334 (1994)) (requiring a warning that "Cigarette Smoking *Is* dangerous to Your Health") (emphasis added).

88. See *Cipollone*, 505 U.S. at 517 ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted."). The Court acknowledged that the legislative history of the 1969 Act indicated that Congress was primarily concerned with positive enactments of state law. See *id.* at 521. The Court, however, refused to give the statute less preemptive effect than the plain language dictated based on the statute's legislative history. See *id.* (citing S. REP. NO. 91-566, at 12 (1969)).

89. See Federal Cigarette Labeling and Advertising Act § 5(a)-(b). The 1965 Act provided that "[n]o statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* § 5(b) (emphasis added).

rette manufacturers include additional warning statements on their packages or in their advertising.⁹⁰

In contrast, the second federal statute contained broader language in its preemption clause, which the Court deemed to indicate that Congress intended to preempt common law damages actions.⁹¹ The second statute prohibited states from imposing requirements or prohibitions relating to the advertising or promotion of cigarettes properly labeled under federal law.⁹² After an evaluation of the nature of common law tort damage awards, the Court concluded that the phrase “requirements or prohibitions” easily encompassed such common law rules.⁹³

In a separate opinion joined by Justices Kennedy and Souter,⁹⁴ Justice Blackmun dissented from the plurality’s finding that the Acts preempted any common law claims.⁹⁵ Justice Blackmun argued that where, as in the second federal statute, Congress spoke directly to the issue of preemption, the Court should not extend the preemptive scope of a statute further than Congress unambiguously provided for in the specific wording of the preemption clause.⁹⁶ In Justice Blackmun’s opinion, the language of the second federal statute was not sufficiently unambiguous to overcome the presumption against preemption dictated by principles of federalism and state sovereignty.⁹⁷ Justice Blackmun found the disparate preemptive effect that the plurality gave to the two statutes “little short of baffling.”⁹⁸

Finally, Justice Blackmun noted that, traditionally, the Court had been reluctant to hold that a state tort claim is preempted when federal law does not create an alternative remedy.⁹⁹ Justice Blackmun argued that

90. See *Cipollone*, 505 U.S. at 518.

91. See *id.* at 521-22.

92. Public Health Cigarette Smoking Act § 5(b) (“No *requirement or prohibition* based on smoking and health shall be imposed under State law with respect to the advertising *or promotion* of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.”) (emphasis added).

93. See *Cipollone*, 505 U.S. at 522 (“[I]t is the essence of the common law to enforce duties that are either affirmative *requirements* or negative *prohibitions*.”). Justice Stevens evaluated each claim, finding preemption where the legal duty predicated the common law damages action constituted a requirement or prohibition based on smoking and health imposed under state law. See *id.* at 523-30.

94. See *id.* at 531-44 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).

95. See *id.* at 531.

96. See *id.* at 533.

97. See *id.*

98. *Id.* at 534.

99. See *id.* at 541.

Congress would not intentionally eliminate the only judicial source of compensation for the victims of cigarette manufacturers' illegal conduct without expressly mentioning common law causes of action in the preemption clause of the statute.¹⁰⁰

Justice Scalia dissented from the plurality's holding,¹⁰¹ arguing that the plurality erred when it narrowly construed the preemptive scope of the statutes.¹⁰² In light of Congress's clearly expressed intent to preempt state law, Justice Scalia argued that, as a test for preemption, the Court should consider whether the law resulting from a common law damages award "practically compels" manufacturers to act in a way that the statute prohibits states from requiring directly.¹⁰³

Only one year later, in *CSX Transportation, Inc. v. Easterwood*,¹⁰⁴ the Supreme Court again found that a federal statute expressly preempted a state tort claim where there was no mention of common law rules in the statute's preemption clause.¹⁰⁵ The Court held that the Federal Railroad Safety Act of 1970 (FRSA)¹⁰⁶ preempted state tort claims where federal regulations governed a particular aspect of train safety.¹⁰⁷

A train owned by CSX Transportation killed Thomas Easterwood when it struck his vehicle at a railway crossing.¹⁰⁸ His widow filed a wrongful-death suit against CSX under state law alleging negligence for "failing to maintain adequate warning devices" and "operating the train at an excessive speed."¹⁰⁹ The Court found that the FRSA did not pre-

100. *See id.* at 542.

101. *See id.* at 544 (Scalia, J., joined by Thomas, J., concurring in part and dissenting in part). Justice Scalia also argued that the first federal statute preempted Cipollone's failure to warn claims. *See id.*

102. *See id.* Justice Scalia argued that the role of the Court is "to interpret Congress's decrees of preemption neither narrowly nor broadly, but in accordance with their apparent meaning." *Id.*

103. *See id.* at 555.

104. 507 U.S. 658 (1993).

105. *See id.* at 664; *see also* Noah, *supra* note 54, at 920 (discussing the Court's decision in *Easterwood*).

106. Pub. L. No. 91-458, 84 Stat. 971 (1970) (codified as amended at 49 U.S.C. §§ 20101-20153 (1994)).

107. *See Easterwood*, 507 U.S. at 664 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522 (1992)). The Act provided that: "[a] State may adopt or continue in force any law, rule, regulation, order, or standard relating to railroad safety until such time as the Secretary [of Transportation] has adopted a rule, regulation, order, or standard covering the subject matter of such State requirement." Federal Railroad Safety Act of 1970 § 205 (1970).

108. *See Easterwood*, 507 U.S. at 661.

109. *Id.*

empt Mrs. Easterwood's state claim regarding warning devices because the warning devices at the crossing were not federally regulated.¹¹⁰

The Court did find, however, that the FRSA preempted Mrs. Easterwood's claim based on excessive speed.¹¹¹ Regulations promulgated under the FRSA prescribe maximum speed limits for all trains, according to the class of track on which they travel.¹¹² Mrs. Easterwood argued that Congress intended the speed regulation to prevent derailments, rather than to promote safety at grade crossings, and, as a result, the speed regulation should not act to preempt her negligence claim.¹¹³ The Court rejected this argument, finding that the FRSA required preemption of state tort claims where a federal regulation has been promulgated covering the subject matter of the claim, regardless of the Department of Transportation's purpose for the regulation.¹¹⁴

II. PREEMPTION UNDER THE MEDICAL DEVICE AMENDMENTS AFTER *CIPOLLONE*

Before the Supreme Court's decision in *Cipollone*, manufacturers did not often raise preemption defenses in the context of the Medical Device Amendments.¹¹⁵ The paucity of preemption defenses was most likely the

110. See *id.* at 672.

111. See *id.* at 676.

112. See 49 C.F.R. § 213.9(a) (1996). Although the train that struck Mr. Easterwood was traveling below the regulation's 60 mile per hour speed limit, Mrs. Easterwood contended that CSX breached a common law duty to operate the train at a safe speed. See *Easterwood*, 507 U.S. at 673.

113. See *Easterwood*, 507 U.S. at 675.

114. See *id.*; *supra* note 107 (providing the preemptive language of the Federal Railroad Safety Act).

115. See Adler & Mann, *supra* note 14, at 916. Some courts found that the MDA did not preempt any state tort claims. See, e.g., *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 668 (D. Md. 1989) (intrauterine device); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1300 (D. Minn. 1988) (intrauterine device); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1282 (Haw.) (pacemaker), *reh'g granted and opinion amended by* 843 P.2d 144 (Haw. 1992); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1233 (Kan. 1987) (intrauterine device).

Other courts have held that the MDA preempted some state tort claims. See Adler & Mann, *supra* note 14, at 916. See, e.g., *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443, 446 (D. Idaho 1990) (tampons); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 15-16 (D. Conn. 1989) (breast implants; finding that § 360k preempts labeling and warning claims but preserving plaintiff's claims because the plaintiff received the implants prior to enactment of the MDA); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477-78 (S.D. Ind. 1988) (tampons; holding that the MDA preempted plaintiff's labeling and warning claims if the manufacturer complied with FDA requirements but preserving design claims); *Stewart v. International Playtex, Inc.*, 672 F. Supp. 907, 910 (D.S.C. 1987) (tampons); *Berger v. Personal Prods., Inc.*, 797 P.2d 1148, 1152 (Wash. 1990) (en banc) (tampons).

result of the courts' previous reluctance to find that federal regulation of a certain field preempted state tort claims, as evidenced by *Silkwood*.¹¹⁶ Since *Cipollone*, courts have seen preemption defenses raised in the medical device context much more frequently, often finding that the MDA preempt state tort claims.¹¹⁷ Although some courts have ruled that the MDA do not preempt any state tort claims, others have held that the MDA preempt all tort claims, and the majority of courts have found that the MDA preempt at least some tort claims against manufacturers of regulated devices.¹¹⁸

A. *King v. Collagen Corp.: The MDA Preempt All Tort Claims Against Manufacturers of Regulated Devices*

In *King v. Collagen Corp.*,¹¹⁹ the United States Court of Appeals for the First Circuit held that the MDA preempted all state tort claims based

116. See *Silkwood v. Kerr-McGee, Corp.*, 464 U.S. 238, 249 (1984). Notwithstanding the holding of *Pacific Gas & Elec. Co. v. State Energy Resources Cons. & Dev. Comm'n*, 461 U.S. 190, 203-04 (1983), that the Atomic Energy Act preempted states from regulating safety aspects of nuclear power plants, the *Silkwood* Court held that a law intended to protect the public does not preempt state tort claims without mention, and without creating an alternative federal remedy. See *Silkwood*, 464 U.S. at 251; see also *supra* Part I.A. (discussing the Supreme Court's decision in *Silkwood*).

117. See, e.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 546 (3d Cir. 1994) (intraocular lens); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16-20 (1st Cir. 1994) (pacemaker); *Hinners v. Optical Radiation Corp.*, 15 F.3d 1096, 1096 (11th Cir. 1994) (per curiam) (intraocular lens); *Duncan v. Iolab Corp.*, 12 F.3d 194, 195 (11th Cir. 1994) (per curiam) (intraocular lens); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 (5th Cir. 1993) (anti-wrinkle treatment); *King v. Collagen Corp.*, 983 F.2d 1130, 1137 (1st Cir. 1993) (anti-wrinkle treatment); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992) (intraocular lens); *Griffin v. Medtronic, Inc.*, 840 F. Supp. 396, 398 (D. Md. 1994) (pacemaker); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1025 (E.D. Mich. 1993) (heart valve); *Reiter v. Zimmer, Inc.*, 830 F. Supp. 199, 203-04 (S.D.N.Y. 1993) (bone cement); *Covey v. Surgidev Corp.*, 815 F. Supp. 1089, 1096 (N.D. Ohio 1993) (intraocular lens). But see *Ginocchio v. Surgikos, Inc.*, 864 F. Supp. 948, 950 (N.D. Cal. 1994) (finding no preemption of state tort claims under the MDA); *Oliver v. Johnson & Johnson, Inc.*, 863 F. Supp. 251, 253 (W.D. Pa. 1994) (prosthetic knee device; requiring counterpart requirements promulgated under the MDA to trigger preemption); *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 635 (S.D. Ohio 1994) (finding no preemption of state tort claims under MDA); *Elbert v. Howmedica, Inc.*, 841 F. Supp. 327, 332 (D. Haw. 1993) (artificial knee); *Lamontagne v. E.I. DuPont de Nemours & Co.*, 834 F. Supp. 576, 586 (D. Conn. 1993) (dental prosthesis), *aff'd*, 41 F.3d 846 (2d Cir. 1994); *Evraets v. Intermedics Intraocular, Inc.*, 34 Cal. Rptr. 2d 852, 855 (Cal. Ct. App. 1994) (intraocular lens; finding no preemption of state tort claims under the MDA); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1282 (Haw. 1992) (pacemaker; finding no preemption of state tort claims under the MDA). See generally *Adler & Mann, supra* note 14, at 916-17 (criticizing the increase in successful preemption defenses after *Cipollone*).

118. See *Adler & Mann, supra* note 14, at 916-17; see also *supra* note 117 (listing cases where courts found preemption).

119. 983 F.2d 1130 (1st Cir. 1993).

on injuries caused by a regulated device.¹²⁰ Jane King received an injection of Zyderm,¹²¹ a Class III medical device manufactured by Collagen Corporation, which, she alleged, caused her to develop an autoimmune disease.¹²² Ms. King filed a complaint alleging seven claims arising out of the Zyderm treatment.¹²³

The First Circuit modeled its preemption analysis after the Supreme Court's analysis in *Cipollone*.¹²⁴ The First Circuit focused solely on § 360k of the MDA,¹²⁵ which defined the statute's preemptive scope, and held that the existence of such a section precluded an implied preemption analysis.¹²⁶ Section 360k prohibited state "requirement[s]" different from or in addition to FDA requirements for a device.¹²⁷ The court looked to the FDA's own interpretation of the preemptive scope of the MDA for guidance.¹²⁸ Based upon the FDA's interpretation, the First Circuit found § 360k to include court-imposed requirements.¹²⁹

Having determined that Congress intended § 360k to preempt state requirements imposed by court decisions, the First Circuit analyzed each of Ms. King's claims to decide whether any claim would impose a new substantive requirement on a device in an area the FDA had already regulated.¹³⁰ Because Zyderm actually passed the rigorous premarket approval process,¹³¹ the court found that the FDA had regulated all aspects

120. See *id.* at 1131.

121. See *id.* at 1132. Zyderm treatments involve the injection of processed cow tissue directly into the patient's skin to smooth wrinkles. See *id.* at 1131.

122. See *id.* at 1132. The disease, dermatomyositis/polymyositis, causes a person's immune system to attack the skin and muscles of the person as if those tissues were a foreign substance. See *id.*

123. See *id.* The claims were strict liability, breach of implied warranty of merchantability, negligence, misbranding and/or mislabeling, misrepresentation, failure to warn, and fraud. See *id.*

124. See *id.* at 1133.

125. 21 U.S.C. § 360k (1994). This section prohibits any state requirement: "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." *Id.*

126. See *King*, 983 F.2d at 1134.

127. See 21 U.S.C. § 360k; see also *supra* note 125 for the text of this provision.

128. See *King*, 983 F.2d at 1134.

129. See *id.* (citing 21 C.F.R. § 808.1(b) (1997), which provides that prohibited state requirements include state requirements emanating from court decisions). *But cf.* *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2258 (1996) (plurality opinion) (stating that requirements emanating from court decisions as referred to in § 808.1(b) encompass only courts' interpretations of positive enactments of law).

130. See *King*, 983 F.2d at 1135.

131. See *id.* at 1132. Zyderm was also subject to revisionary requirements after the FDA granted the original approval. See *id.*

of the safety, effectiveness, labeling, and manufacture of the device.¹³² Thus, any successful claim against the manufacturer of the device would constitute an additional state requirement and, therefore, would be preempted.¹³³

B. Feldt v. Mentor Corp.: The MDA Preempt Some Tort Claims Against Manufacturers of Regulated Devices

In *Feldt v. Mentor Corp.*,¹³⁴ the United States Court of Appeals for the Fifth Circuit held that the MDA preempted state failure to warn claims but permitted state design defect claims.¹³⁵ Sam Feldt was the recipient of a GFS penile prosthesis, a Class III device manufactured by the Mentor Corporation.¹³⁶ Less than three years after the implantation of the device in Mr. Feldt, the device ceased to function.¹³⁷ Mr. Feldt sued Mentor claiming, inter alia, failure to warn and defective design.¹³⁸

The Fifth Circuit began its preemption analysis with the presumption that the state law duties behind Mr. Feldt's claims constituted requirements relating to the safety and effectiveness of the GFS.¹³⁹ The court

132. See *id.* at 1135-36. The First Circuit found that the MDA preempted King's strict liability claim. See *id.* at 1135. The court held that by granting premarket approval, the FDA had determined Zyderm to be safe and effective for the device's intended purpose. See *id.* The court explained that to impose strict liability on the corporation would be to impose additional state requirements relating to the safety and effectiveness of the device. See *id.* With regard to King's breach of express warranty claims, the court found the MDA preempted such claims because they arose directly from the labeling and packaging of the device. See *id.* The court held that the MDA also preempted King's breach of implied warranty of merchantability claim because such a claim arose out of state contract law and also would impose additional state requirements on the device. See *id.* at 1135-36.

The court found all of King's negligence claims to relate to the design, manufacture, and labeling of the device, and therefore held that the MDA preempted such claims. See *id.* at 1136. Furthermore, the court found that the MDA preempted King's claim based on product misbranding, misrepresentation, and failure to warn. See *id.* The court reasoned that FDA approval of a product's labeling constitutes a determination that the labeling is not false or misleading. See *id.* Absent allegations that Collagen failed to use FDA-approved packaging and labeling, any such claim would impose additional or different requirements on the device than those imposed by the FDA. See *id.* All of King's remaining claims were dismissed for similar reasons. See *id.*

133. See *id.* at 1135-36.

134. 61 F.3d 431 (5th Cir.), *vacated*, *Mentor Corp. v. Feldt*, 116 S. Ct. 2575 (1996).

135. See *id.* at 438.

136. See *id.* at 432-33.

137. See *id.* at 432. After the initial failure, the device had to be removed and replaced. See *id.* Feldt claimed that the defect in the device caused him embarrassment and trauma, and contributed to the termination of his engagement. See *id.*

138. See *id.* at 433 n.1. Feldt's claims also included negligence, strict liability, breach of warranty, and violations of the Texas Deceptive Trade Practices Act. See *id.* at 432-33.

139. See *id.* at 434.

therefore limited its inquiry to determining whether the MDA imposed any requirements on the GFS penile prosthesis.¹⁴⁰ In contrast to the device at issue in *King v. Collagen Corp.*,¹⁴¹ the GFS was not subjected to the rigorous premarket approval process.¹⁴² Instead, the FDA allowed the device to enter the market through the premarket notification process because Mentor demonstrated that the prosthesis was substantially equivalent to a device on the market prior to the enactment of the MDA.¹⁴³

The court first addressed Mr. Feldt's argument that the premarket notification process did not invoke § 360k preemption.¹⁴⁴ The court rejected this argument because it found, based on its earlier holding in *Reeves v. AcroMed Corp.*,¹⁴⁵ that: (1) the existence of any federal requirement triggers a preemption analysis; and (2) that the premarket notification process imposes requirements on a device, including labeling and warning requirements.¹⁴⁶ As a result, the court held that the MDA preempted

140. See *id.* (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir. 1993) (explaining the Fifth Circuit test for § 360k preemption)).

141. 983 F.2d 1130 (1st Cir. 1993).

142. See *Feldt*, 61 F.3d at 434.

143. See *id.* See generally *supra* notes 23-24 and accompanying text (discussing the premarket notification process).

144. See *Feldt*, 61 F.3d at 434-36. Feldt argued that the regulations applicable to the device through the premarket notification process were intended to "identif[y] and clas-sif[y]" the device, rather than promote its safety, and therefore should not "be construed as federal requirements within the meaning of section 360k." *Id.* at 435.

145. 44 F.3d 300, 307 (5th Cir. 1995) (finding preemption of a failure-to-warn claim against the manufacturer of a Class III device that entered the market through the pre-market notification process), *cert. denied*, 515 U.S. 1104 (1995). In *Reeves*, a neurosurgeon "implanted metal bone plates and screws manufactured by AcroMed" in Dorothy Reeves' back to facilitate fusion of her vertebrae. *Id.* at 302. Six months after the surgery, Reeves experienced severe back pain. See *id.* Reeves filed suit alleging that AcroMed's metal bone implant had broken and, thus, prevented her spine from fusing. See *id.* Included in Reeves' complaint was a claim that AcroMed failed to warn her that the FDA had approved the metal bone implant for use in the spine only as part of an experimental study. See *id.* Based on Reeves' failure-to-warn claim, a jury awarded her \$475,000. See *id.* at 302.

Like the GFS, the AcroMed bone implant entered the market through the premarket notification process. See *id.* at 305. The *Reeves* court acknowledged that completion of the premarket notification process does not constitute official FDA approval of a device. See *id.* The premarket notification process, however, does involve extensive FDA scrutiny and approval of the labeling of the device. See *id.* Thus, the Fifth Circuit concluded that because the FDA had promulgated requirements on the labeling of the AcroMed device within the meaning of § 360k, Reeves' failure-to-warn claim was preempted. See *id.*

146. See *Feldt*, 61 F.3d at 435 (citing *Reeves*, 44 F.3d at 305). In 21 C.F.R. § 801.109(c) (1997), the FDA requires all Class III device labeling to contain (1) usage information, "including indications, effects, routes, methods, and frequency and duration of administra-

Feldt's failure-to-warn claim.¹⁴⁷

Noting that the existence of some FDA requirements applicable to the GFS did not necessarily preclude all of Mr. Feldt's claims,¹⁴⁸ the court then considered the preemption of claims based on defective design.¹⁴⁹ The court found that the premarket notification process did not constitute an affirmation by the FDA of the safety or effectiveness of the GFS design.¹⁵⁰ Accordingly, the court held that the MDA did not preempt Mr. Feldt's defective design claims.¹⁵¹

C. Kennedy v. Collagen Corp.: No Preemption of State Tort Claims under the MDA

In sharp contrast to the First Circuit's holding in *King*, the Ninth Circuit, in *Kennedy v. Collagen Corp.*,¹⁵² held that the MDA did not preempt any tort claims against the manufacturer of a Class III device.¹⁵³ Contrary to the courts finding preemption of tort claims under the MDA, the Ninth Circuit understood the FDA's interpretation of the preemptive scope of the MDA to preserve all state tort claims.¹⁵⁴ In *Kennedy*, as in *King*, the state tort claims arose when the plaintiff suffered injuries from a Zyderm collagen implant, a Class III medical device.¹⁵⁵

The Ninth Circuit found that Congress's preemptive language was ambiguous and, therefore, looked to the FDA regulation defining the preemptive scope of § 360k for assistance.¹⁵⁶ The FDA regulation preserved state requirements of "general applicability,"¹⁵⁷ which, the court con-

tion," and (2) warning information including, "relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (1997). Premarket notification submissions are screened for compliance with the labeling requirements. *See id.* § 807.87(e).

147. *See Feldt*, 61 F.3d at 436.

148. *See id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523-28 (1992)).

149. *See id.*

150. *See id.* at 437. The court found that the MDA's General Manufacturing Principles, applicable to all Class III devices, do not impose requirements on the design of the devices. *See id.*

151. *See id.* at 437-38. The court deemed Feldt's claim of breach of implied warranty of merchantability to encompass a defective design claim. *See id.* at 436-37.

152. 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996).

153. *See id.* at 1458-59.

154. *See id.* at 1460.

155. *See id.* at 1454-55; *see also supra* notes 121-22 and accompanying text (discussing the Zyderm treatment and associated injuries).

156. *See Kennedy*, 67 F.3d at 1457. "As long as the FDA has propounded any 'reasonable interpretation' of the provision, this Court has no cause to overturn the agency's interpretation in favor of its own." *Id.* (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)).

157. *See* 21 C.F.R. § 808.1(d) (1997).

cluded, encompassed common law claims.¹⁵⁸ The court also found that the premarket approval process was not a “specific requirement . . . applicable to a particular device.”¹⁵⁹ Holding otherwise, the court explained, would result in federal preemption of all state tort claims against manufacturers of devices with premarket approval, and leave the injured party without any remedy.¹⁶⁰ In light of the Supreme Court’s decision in *Silkwood* and Congress’s stated purpose for enacting the MDA, consumer protection,¹⁶¹ the Ninth Circuit held that the MDA did not preempt tort claims against manufacturers of devices that had received premarket approval.¹⁶²

III. *MEDTRONIC, INC. V. LOHR*: SHRINKING THE PREEMPTION SHIELD FOR MANUFACTURERS OF “SUBSTANTIALLY EQUIVALENT” DEVICES

The Supreme Court seized the opportunity presented by *Medtronic, Inc. v. Lohr*¹⁶³ to define the extent to which the MDA preempt state common law claims.¹⁶⁴ In *Medtronic*, Lora Lohr sought to recover for injuries allegedly caused by the failure of Medtronic’s Model 4011 pacemaker lead, claiming negligent design, negligent manufacture, and failure to warn.¹⁶⁵ The 4011 pacemaker lead, a Class III medical device, came to market through the premarket notification process because the FDA deemed it “substantially equivalent” to a device marketed prior to the enactment of the MDA.¹⁶⁶ After convincing the FDA that the 4011 lead was substantially equivalent to an existing device, Medtronic needed to comply only with the general federal regulations applicable to all medical

158. See *Kennedy*, 67 F.3d at 1459. The court reasoned that, although common law claims arise as a response to an injury caused by a particular device, “state common law does not relate solely to or regulate any *particular* device or product to the exclusion of other devices or products.” *Id.* Additionally, the court explained, unlike positive enactments of state law, defendants in common law damages actions have the ability to decide how to respond to an unfavorable judgment. See *id.*

159. *Id.* The court reasoned that, because all Class III devices must obtain premarket approval before reaching the public market, premarket approval alone does not constitute a “specific requirement” under 21 C.F.R. § 808.1(d) (1997). See *id.* (emphasis omitted).

160. See *id.*

161. See *id.* (citing 43 Fed. Reg. 18,663 (1978)).

162. See *id.* at 1459-60. The court distinguished the purpose of direct state regulation--to govern the actions of manufacturers before releasing their products to the public--and the purpose of state common law damages actions--to provide compensation for injured consumers. See *id.* at 1459. Thus, the court reasoned, Congress did not intend to preempt common law damages actions with an Act designed to protect consumers. See *id.*

163. 116 S. Ct. 2240 (1996).

164. See *id.* at 2250.

165. See *id.* at 2248.

166. See *id.*

devices, including Good Manufacturing Practices and labeling requirements.¹⁶⁷

The Federal District Court for the Middle District of Florida found that § 360k preempted all counts of Ms. Lohr's complaint and dismissed the case.¹⁶⁸ The United States Court of Appeals for the Eleventh Circuit reversed in part and remanded in part.¹⁶⁹ The court concluded that the MDA did not preempt Ms. Lohr's negligent design claims because the premarket notification process did not impose federal requirements on the design of the 4011 lead.¹⁷⁰ The court found, however, that the MDA

167. See *id.* at 2256. The Good Manufacturing Practices impose duties on medical device manufacturers such as instituting a quality assurance program; maintaining an adequate organizational structure to ensure that workers who come in contact with a device are clean, healthy, and suitably dressed; providing sufficient personnel training; and having adequate buildings and environmental controls to ensure a safe product. See *id.* at 2256 n.17 (citing 21 C.F.R. §§ 820.5, 820.20, 820.25, 820.40, 820.46, 820.60 (1997)).

168. See *id.* at 2249.

169. See *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1352 (11th Cir. 1995), *aff'd in part, rev'd in part*, 116 S. Ct. 2240 (1996). The only issue on appeal was whether the district court properly held that § 360k preempted all state common law tort claims against the manufacturer of a Class III medical device that arrived on the market via the premarket notification process. See *id.* at 1341. The Eleventh Circuit Court of Appeals began its discussion by analyzing the preemptive scope of § 360k. See *id.* at 1342. Prior to hearing *Medtronic*, the Eleventh Circuit, in *Duncan v. Iolab Corp.*, 12 F.3d 194, 195 (11th Cir. 1994), adopted the Seventh Circuit's reasoning in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1331 (7th Cir. 1992), that the term "state requirement" in § 360k encompasses state common law damages actions. See *Lohr*, 56 F.3d at 1342. To determine the type of requirements that must be applicable to a device under the MDA to trigger preemption, the Eleventh Circuit turned to the FDA's preemption regulations because it found Congress's language ambiguous. See *id.* at 1344. Relying on the FDA's preemption regulations, 21 C.F.R. § 808.1(d), the court concluded that a federal requirement must be specifically applicable to a particular device in order to trigger preemption. See *id.*

170. See *Lohr*, 56 F.3d at 1347-49. Medtronic made four arguments in support of its contention that the premarket notification process imposed specific requirements on the Model 4011 pacemaker lead. See *id.* at 1348-49. First, Medtronic argued that the FDA's approval of the pacemaker lead's Premarket Notification Summary constituted a finding that the device was safe and effective. See *id.* at 1348. The Eleventh Circuit rejected this argument, reasoning that the premarket notification process focused on a device's similarity to an existing device not yet proven safe or effective. See *id.* The court found, therefore, that the premarket notification process alone did not impose specific requirements on the design of the device. See *id.* at 1349. See generally *supra* notes 23-24 and accompanying text (discussing the premarket notification process).

Second, Medtronic argued that the MDA implicitly recognized pre-MDA devices as safe and effective. See *Lohr*, 56 F.3d at 1349. The court rejected this argument because it found no indication in either the text or legislative history of the MDA that the "grandfathering" of pre-MDA devices constituted a finding of safety or effectiveness. See *id.* The court described the MDA as a balancing of two interests: the protection of consumers from unsafe devices and the fostering of the development of innovative medical devices through the assurance of a predictable regulatory and liability climate. See *id.* (citing S. REP. NO. 94-33, at 10 (1975), H.R. REP. NO. 94-853, at 10-11 (1976)). The court believed

general manufacturing and labeling requirements applicable to the pacemaker lead did preempt Ms. Lohr's negligent manufacturing and labeling claims.¹⁷¹

In *Medtronic*, the Supreme Court decided four issues over which the lower courts were split.¹⁷² First, the plurality held that § 360k did not preempt all tort claims by an injured plaintiff against a medical device manufacturer.¹⁷³ Second, the plurality held that the premarket notification process did not impose requirements on the design of medical devices and, consequently, § 360k did not preempt defective design claims against manufacturers of devices marketed through that process.¹⁷⁴ Third, the plurality held that § 360k did not preempt claims based on alleged violations of FDA regulations.¹⁷⁵ Finally, the plurality held that the Good Manufacturing Practices and labeling and warning requirements applicable to all medical devices through the MDA did not constitute requirements applicable to a device under § 360k, and, therefore, § 360k

that to grant the same protection to manufacturers of grandfathered devices, which were not subject to the increased controls of the MDA, would be to give those manufacturers a regulatory windfall. *See id.*

Third, Medtronic argued that the FDA's continuing surveillance of the design and labeling of the device constituted requirements under the MDA. *See id.* (citing 21 C.F.R. § 807.81(a)(3)(i) (1997) (requiring manufacturers to submit any proposed design changes to the FDA for approval), and 21 C.F.R. § 895.25 (1997) (empowering the FDA to require labeling changes)). The court rejected this argument, reasoning that such provisions are general requirements because the provisions are not restricted to a particular device. *See id.*

Fourth, Medtronic argued that the classification procedures created under the MDA impose specific requirements on devices. *See id.* (citing 21 U.S.C.A. § 360c (West Supp. 1997) (designating three classes of devices) and 21 C.F.R. § 860.7 (1997) (outlining the MDA's classification scheme)). The court rejected this argument, reasoning that a requirement is "something called for or demanded" and that classification does not create demands on Medtronic. *Id.*

171. *See Lohr*, 56 F.3d. at 1350. *See generally* 21 C.F.R. § 801.109 (1997) (requiring all Class III medical devices to comply with FDA labeling requirements); 21 C.F.R. §§ 820.1-198 (listing Good Manufacturing Practices (GMPs) applicable to all Class III devices under the MDA); *supra* note 167 (discussing the GMPs). With regard to the negligent manufacturing claims, the court explained that even though the GMPs were not device-specific requirements, the GMPs were specific to manufacturing and created standards for the entire manufacturing process. *See Lohr*, 56 F.3d at 1350. Similarly, the court found the labeling regulations to impose specific standards that manufacturers must follow when creating the labeling for a device, notwithstanding the applicability of the requirements to other devices. *See id.*

172. *See Medtronic*, 116 S. Ct. at 2253-55, 2358.

173. *See id.* at 2253 (plurality opinion).

174. *See id.* at 2254.

175. *See id.* at 2255.

did not preempt state law claims based on failure to warn or negligent manufacturing.¹⁷⁶

A. The Plurality: No Preemption without Device-Specific Regulations

Writing for a plurality of the Court, Justice Stevens began by acknowledging that the Court was faced with the task of interpreting the scope of Congress's intent to preempt state law.¹⁷⁷ Justice Stevens explained that two presumptions informed the Court's interpretation: first, that federal regulations do not supersede the police powers of the states unless Congress makes its purpose to supersede "clear and manifest,"¹⁷⁸ and second, that Congress's purpose is the "ultimate touchstone" in any preemption analysis.¹⁷⁹ Based on these two presumptions, the plurality rejected Medtronic's argument that § 360k preempted all common law causes of action against medical device manufacturers.¹⁸⁰

First, the plurality distinguished § 360k from the preemption clause at issue in *Cipollone*.¹⁸¹ Second, the plurality explained that insulating device manufacturers from tort claims was contrary to the primary purpose of the MDA, consumer protection.¹⁸² Third, Justice Stevens reasoned that the language of § 360k was not sufficiently unambiguous to overcome the presumption against preemption of state tort claims.¹⁸³ Justice

176. *See id.* at 2258.

177. *See id.* at 2250.

178. *Id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

179. *See id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).

180. *See id.* at 2251 (plurality opinion).

181. *See id.* at 2251-52; *see also Cipollone*, 505 U.S. at 521-22. Significant to the Court's holding in *Cipollone*, the plurality explained, was the narrow focus of the preemption clause at issue. *See Medtronic*, 116 S. Ct. at 2252 (plurality opinion). The plurality explained that the preemption clause in the Public Health Cigarette Smoking Act of 1969 "was targeted at a limited set of state requirements—those 'based on smoking and health'—and then only at a limited subset of the possible applications of those requirements—those involving the 'advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of' the federal statute." *Id.* The narrow focus of the Act enabled *Cipollone* to maintain some common law claims. *See id.*

The plurality explained that to accept Medtronic's broad reading of the preemptive scope of the MDA would require the Court to intrude impermissibly into state sovereignty and also preclude Lohr from obtaining any remedy for her injuries. *See id.* Due to the combination of the ambiguity of § 360k and the potentially broad preemptive effect of the statute, the plurality determined that Congress had not indicated a clear intent to preempt all state tort claims. *See id.*

182. *See id.*; *see also Medical Device Amendments of 1976*, Pub. L. No. 94-295, 90 Stat. 539 (1976) (stating in the preamble that the purpose of the Act is "to provide for the safety and effectiveness of medical devices intended for human use").

183. *See Medtronic*, 116 S. Ct. at 2251 (plurality opinion). Justice Stevens acknowledged that the Court, in an opinion authored by him in *Cipollone*, had held that a statute

Stevens explained that if Congress had intended to prohibit state law causes of action, it should have prohibited "remedies" under state law, rather than "requirements."¹⁸⁴ Finally, the plurality examined the legislative history of § 360k and found no indication that the provision was intended to preempt all state tort claims.¹⁸⁵ The plurality found that Congress enacted § 360k to alleviate its concerns regarding the risk of additional or inconsistent federal or state regulation rather than in an effort to eliminate preexisting common law duties.¹⁸⁶

The plurality next considered whether the Eleventh Circuit correctly preserved Ms. Lohr's claims based on negligent design.¹⁸⁷ The viability of Ms. Lohr's design claim depended on whether the premarket notification process imposed federal safety requirements on the device's design.¹⁸⁸ The plurality held that § 360k did not preempt the negligent design claim, reasoning that the premarket notification process did not concern the safety of the pacemaker lead and had no impact on the design of the device.¹⁸⁹ The premarket notification process, the plurality found, merely compared the 4011 lead with a pre-1976 lead that the FDA had not tested for safety.¹⁹⁰

The plurality next addressed Ms. Lohr's argument that, even if FDA requirements regarding the manufacturing and labeling of the 4011 lead did exist, as the Eleventh Circuit held, § 360k should not preempt the claims based on alleged violations of those requirements.¹⁹¹ The plurality

which precluded requirements under state law also preempted state tort claims. *See id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992)). Justice Stevens reconciled the two opinions, explaining that reading the term "requirement" broadly in *Cipollone* did not result in a complete denial of judicial remedies for plaintiffs, as such a reading would require in *Medtronic*. *See id.* at 2251-52.

184. *See id.* at 2251.

185. *See id.* at 2253.

186. *See id.*; *see also* 122 CONG. REC. 5850, 5855 (Mar. 9, 1976) (statement of Rep. Collins) ("opposing further 'redundant and burdensome Federal requirements'" while "discussing efforts taken in the MDA to protect small businesses from the additional requirements of the Act"). The plurality found no reference to concerns that tort actions would impede the development of medical devices in the legislative history of the Act. *See Medtronic*, 116 S. Ct. at 2253 (plurality opinion). Rather, the plurality explained, "[t]o the extent that Congress was concerned about protecting the [medical device] industry, that intent was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision" *Id.*

187. *See Medtronic*, 116 S. Ct. at 2254.

188. *See id.*

189. *See id.*

190. *See id.*; *see also* Adler, *supra* note 17, at 516 (noting that if the pre-1976 device "poses a severe risk or is ineffective," then the substantially equivalent device may also be "risky or ineffective").

191. *See Medtronic*, 116 S. Ct. at 2255. The Eleventh Circuit concluded that Lohr's

agreed, finding that a damages remedy does not impose additional requirements on a device but, rather, provides an incentive for manufacturers to comply with existing requirements.¹⁹² The plurality determined that § 360k did not prohibit state damages remedies for breach of common law duties that parallel federal requirements, and that common law claims based on violations of federal requirements were parallel to the federal requirements.¹⁹³

The plurality's final consideration focused on whether § 360k preempted Ms. Lohr's manufacturing or labeling claims.¹⁹⁴ The plurality analyzed the language of § 360k¹⁹⁵ and the FDA regulations interpreting that section,¹⁹⁶ finding that both a state and federal requirement must be specifically applicable to the device in question before § 360k triggers preemption.¹⁹⁷ The plurality held that § 360k did not preempt Ms. Lohr's manufacturing and labeling claims because the relevant MDA provisions applied to all medical devices and, therefore, were not the product of the federal government having balanced the competing interests relevant to the requirement.¹⁹⁸ The plurality also noted that, because Florida did not

claims were preempted on the basis of the pleadings so it did not determine whether the claims, in fact, included alleged violations of FDA regulations. *See id.* at 2255-56.

192. *See id.* at 2255. The plurality then addressed the FDA's interpretation of the scope of § 360k and found that the Agency's interpretation supported the conclusion that the section did not preempt claims based on violations of existing requirements. *See id.* at 2255-56; *see also* 21 C.F.R. § 808.1(d)(2) (1997) (providing that "[federal law] does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act").

193. *See Medtronic*, 116 S. Ct. at 2255. The plurality acknowledged that a state law cause of action alleging violations of duties created by federal law may include *additional* elements, such as proof that the violations were the result of negligent conduct or that the violations created an unreasonable danger for recipients of the device. *See id.* The Court found, however, that the additional elements would make the state requirements narrower than the federal requirements. *See id.* Despite its finding that the narrower state requirements differed from the federal requirements in a literal sense, the plurality found that the difference did not provide sufficient reason to warrant preemption. *See id.* *See generally* 21 U.S.C. § 360k(a)(1) (1994) (prohibiting state requirements that are different from existing federal regulations).

194. *See Medtronic*, 116 S. Ct. at 2256.

195. 21 U.S.C. § 360k(a)(1) (prohibiting state requirements "with respect to a device . . . different from, or in addition to, any requirement applicable under this [Act] to the device" (emphasis added)).

196. *See* 21 C.F.R. § 808.1(d) (1997).

197. *See Medtronic*, 116 S. Ct. at 2257-58.

198. *See id.* at 2258. This line of reasoning, in which courts focus on the impact of state law on federal regulatory schemes is known as the "delicate balance" theory of preemption. *See Corboy & Smith, supra* note 7, at 461. Commentators Philip Corboy and Todd Smith suggest that courts adopting the delicate balance theory of preemption may find preemption even when congressional intent to preempt state law is absent or ambiguous, thereby departing from the principle that congressional intent is the "ultimate touchstone"

specifically develop the general common law requirements underlying Ms. Lohr's claims for medical devices, such requirements were too general to fall within the preemptive scope of § 360k as envisioned by both Congress and the FDA.¹⁹⁹

Significantly, the plurality declined to rule on whether common law duties *never* constitute requirements under § 360k.²⁰⁰ The plurality did take notice of 21 C.F.R. § 808.1(b), an FDA regulation providing that § 360k preempts state law established by court decision,²⁰¹ which some courts had used as a basis for preemption.²⁰² The plurality determined, however, that in 21 C.F.R. § 808.1(b), the FDA referred to court decisions construing positive enactments of law.²⁰³

in preemption cases. *See id.* But cf. Mary Ann K. Bosack, *Cigarette Act Preemption—Refining the Analysis*, 66 N.Y.U. L. REV. 756, 798 (1991) (arguing in favor of the “delicate balance” theory of preemption).

199. *See Medtronic*, 116 S. Ct. at 2258. However, the plurality already had conceded that state requirements of general applicability are subject to preemption if they effectively establish a “substantive requirement for a specific device.” *Id.* at 2257.

200. *See id.* at 2258-59 (plurality opinion). The plurality declined to rule on whether common law duties never constitute requirements under § 360k for two reasons. *See id.* at 2259. First, because the MDA did not preempt any of Ms. Lohr's claims, the plurality did not find it necessary to resolve hypothetical cases. *See id.* Second, because of the substantial importance of “device-specificity” in the plurality's construction of § 360k, the plurality concluded that future instances where the MDA would preempt common law claims would be very rare. *See id.* at 2259. The plurality did note, however, that the Court's opinion in *Cipollone*, holding that common law duties impose requirements on manufacturers, was not dispositive of the issue because of the significant differences between § 360k and the statute at issue in *Cipollone*. *See id.* at 2258 n.19; *see also supra* note 181 (discussing the *Medtronic* plurality's comparison of the MDA and the Public Health Cigarette Smoking Act of 1969).

201. *See Medtronic*, 116 S. Ct. at 2258 (plurality opinion); 21 C.F.R. § 808.1(b) (1997) (describing § 360k(a) as prohibiting state requirements “having the force and effect of law (whether established by statute, ordinance, regulation, or court decision)”). In 21 C.F.R. § 808.1(d)(1), however, the FDA interprets § 360k(a) as not preempting:

[s]tate or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

Id. As some commentators note, if § 360k(a) “does not preempt general bodies of law such as the UCC . . . [then], *a fortiori*, it would not preempt broader, more established bodies of general law such as common law torts.” Adler & Mann, *supra* note 14, at 940.

202. *See King v. Collagen Corp.*, 983 F.2d 1130, 1134, 1137 (1st Cir. 1993); *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 755, 761 (S.D.N.Y. 1994); *Lamontagne v. E.I. DuPont de Nemours & Co.*, 834 F. Supp. 576, 582-86 (D. Conn. 1993), *aff'd*, 41 F.3d 846 (2d Cir. 1994); *Cameron v. Howmedica, Div. of Pfizer Hosp. Prods. Group, Inc.*, 820 F. Supp. 317, 319, 231 (E.D. Mich. 1993).

203. *See Medtronic*, 116 S. Ct. at 2258 (plurality opinion) (citing 42 Fed. Reg. 30,383, 30,385 (1977)). But *see Herrmann & Ritts, supra* note 18, at 17 (arguing that state common law principles such as “implied warranty law . . . [would remain] enforceable until it

Justice Breyer authored a concurring opinion to emphasize that the MDA may preempt state law tort actions in certain circumstances.²⁰⁴ Citing *Cipollone*, Justice Breyer argued that the legal duties arising out of tort actions do constitute state-imposed requirements within the meaning of "requirement" under § 360k.²⁰⁵ Accordingly, he deemed the MDA's prohibition on any additional or different state requirements to preempt state tort actions alleging that federally mandated conduct is negligent.²⁰⁶

B. The Dissent: The MDA Expressly Preempt Common Law Claims

Justice O'Connor, in dissent, argued that the Court should not look beyond the language of § 360k to determine the preemptive scope of the MDA.²⁰⁷ First, relying on *Cipollone*, the dissent determined that all common law claims constitute requirements because the imposition of an obligation to pay damages is an effective means of controlling conduct.²⁰⁸ Relying on the plain language of § 360k, the dissent argued that any common law claim that resulted in a requirement different from or in

required a medical device manufacturer to redesign its product," at which point the state law would be displaced).

204. See *Medtronic*, 116 S. Ct. at 2259 (Breyer, J., concurring in part and concurring in the judgment).

205. See *id.*

206. See *id.* Justice Breyer argued that excluding requirements arising out of state tort actions from § 360k's prohibition on additional or different state requirements would have the effect of granting a single state jury more power to regulate medical devices than state legislators and administrators. See *id.* Justice Breyer specifically disagreed with the plurality's conclusion that future incidents of preemption under the MDA would be rare. See *id.* at 2262. Justice Breyer also found the portion of the plurality opinion that differentiated between § 360k and the preemption statute at issue in *Cipollone* to be irrelevant. See *id.* at 2261-62.

Having concluded that the plain language of § 360k preempted some state tort actions, Justice Breyer then considered whether the MDA preempted Lohr's claims. See *id.* at 2260. Justice Breyer found the language of § 360k to be ambiguous regarding when federal requirements preempt state requirements. See *id.* ("The words 'any [state] requirement' and 'any [federal] requirement,' for example, do not tell us which requirements are at issue, for every state requirement that is not identical to even one federal requirement is 'different from, or in addition to' that single federal requirement . . ."). Like the plurality, Justice Breyer looked to the FDA for guidance on the preemptive scope of § 360k. See *id.* Justice Breyer reasoned that, in addition to the statute's inherent ambiguity, deference to the FDA was particularly warranted because the FDA is fully responsible for administering the MDA and, therefore, has a "special understanding" of the effect of state regulations on federal objectives. See *id.*

207. See *id.* at 2262 (O'Connor, J., concurring in part and dissenting in part). Chief Justice Rehnquist and Justices Scalia and Thomas joined Justice O'Connor in her opinion. See *id.*

208. See *id.* (citing *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)).

addition to a federal requirement was subject to preemption.²⁰⁹ The dissent criticized the plurality's deference to the FDA regulation requiring device-specific state and federal requirements to trigger preemption.²¹⁰

The dissent then determined which of Ms. Lohr's claims were preempted by the MDA, without regard to device specificity.²¹¹ Justice O'Connor argued that § 360k preempted only Ms. Lohr's negligent manufacturing and failure to warn claims.²¹² The dissent reasoned that a resolution of such claims against the defendant "would compel Medtronic to comply with requirements different from or in addition to those required by the FDA."²¹³

IV. MEDTRONIC, INC. v. LOHR: PRESERVING THE PREEMPTION DEFENSE FOR MANY FEDERALLY REGULATED INDUSTRIES

In *Medtronic v. Lohr*,²¹⁴ the Supreme Court resolved the conflict among the federal circuit courts over the MDA's preemptive effect on state tort claims.²¹⁵ The plurality concluded that the MDA did not preempt state tort claims against the manufacturer of a device unless there was a federal requirement specifically applicable to that device under the MDA.²¹⁶ The plurality also held that the MDA did not preempt state tort claims alleging that a manufacturer violated federal regulations.²¹⁷ This decision will have considerable impact on the lower courts' preemption analyses in future medical device cases.

209. See *id.* at 2263.

210. See *id.*; see also 21 C.F.R. § 808.1(d)(1) (1997); *supra* note 201 (providing the relevant text of the regulation).

211. See *Medtronic*, 116 S. Ct. at 2263-64 (O'Connor, J., concurring in part and dissenting in part).

212. See *id.* at 2264. The dissent agreed with the plurality's findings regarding Lohr's claims based on both defective design and alleged violations of federal regulations. See *id.* at 2263-64. The dissent explained that § 360k did not preempt Lohr's defective design claims because the premarket notification process did not impose requirements on the design of the device. See *id.* at 2264. The dissent reasoned that § 360k did not preempt Lohr's claims based on alleged violations of federal regulations because such claims would not impose requirements on Medtronic different from or in addition to federal requirements. See *id.* Additionally, the dissent noted that § 360k did not prohibit "different or additional remedies" imposed under state law. See *id.*

213. *Id.* at 2264.

214. 116 S. Ct. 2240 (1996).

215. See *supra* Part II (discussing the preemptive effect given to the MDA by some federal circuit courts).

216. See *Medtronic*, 116 S. Ct. at 2257.

217. See *id.* at 2255-56. The dissent agreed with the plurality's holding that § 360k did not preempt Lohr's claims alleging that Medtronic violated federal requirements. See *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

The three opinions of the Court also indicate how the Supreme Court likely will rule on the preemptive effect of other federal statutes on state tort claims.²¹⁸ Four Justices properly sought to return to the *Silkwood* line of reasoning, which treated tort law as an insufficiently direct form of state regulation to warrant preemption.²¹⁹ These four Justices properly found the language of the MDA's preemption clause to be too ambiguous to overcome a presumption against preemption.²²⁰ A majority of the Court, however, continues to subscribe to the Court's treatment of tort claims in *Cipollone*.²²¹

A. Impact on Future Medical Device Cases

1. Substantially Equivalent Devices

The Court's holding in *Medtronic* eliminates a preemption defense for manufacturers of medical devices that have bypassed the premarket approval process and have come to the market as substantially equivalent devices.²²² The plurality's finding that the premarket notification process does not impose requirements on the design of medical devices²²³ will

218. See, e.g., Radiation Control for Health and Safety Act of 1968 (RCHSA), Pub. L. No. 90-602, 82 Stat. 273 (1968) (codified as amended at 21 U.S.C. § 360kk(a)(1) (1994)) (cellular phones); National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, 80 Stat. 718 (1966) (codified as amended at 15 U.S.C. §§ 1381-1431 (1988)); Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Pub. L. No. 125-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (1994)). The RCHSA authorizes the FDA to "prescribe performance standards . . . to control the emission of electronic product radiation from such products if it determines that such standards are necessary for the protection of the public health and safety." 21 U.S.C. § 360kk(a)(1). Additionally, when the FDA has promulgated a standard under the RCHSA, the Act prohibits states from imposing standards that conflict with the federal standard. See 21 U.S.C. § 360ss.

The preemptive scope of the RCHSA may have significant consequences because scientists have not yet determined whether the increasingly popular phones are safe. See Mike Mills, *Still Waiting for the Call: Do Cellular Phones Cause Brain Tumors? Researchers' Inability to Provide an Answer So Far is Only Raising More Questions*, WASH. POST, Apr. 6, 1997, at H1. Cellular telephones emit radiation that allegedly causes brain tumors. See *id.* The number of Americans who use cellular phones has increased from roughly fifteen million in 1993 to roughly 45 million in 1997, the majority of whom opt for hand-held models that place the radiation emitting antennas next to the brain. See *id.* See generally *Verb v. Motorola, Inc.*, 672 N.E.2d 1287 (Ill. App. Ct. 1996) (involving an action against a telephone manufacturer alleging that cellular phones should be accompanied by safety warnings).

219. See *Medtronic*, 116 S. Ct. at 2251 (plurality opinion); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984).

220. See *Medtronic*, 116 S. Ct. at 2251 (plurality opinion).

221. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523 (1992).

222. See *Medtronic*, 116 S. Ct. at 2254; *id.* at 2264 (O'Connor, J., concurring).

223. See *id.* at 2254; *id.* at 2264 (O'Connor, J., concurring).

preserve future negligent design claims brought against manufacturers of non-approved devices.²²⁴ The Court's conclusion that the requirements applicable to all non-approved medical devices through the MDA are too general to warrant preemption²²⁵ likewise will preserve manufacturing and labeling claims against manufacturers of non-approved devices.

2. Future Unclear for Investigational and FDA-Approved Devices

A preemption defense clearly will remain available for manufacturers of medical devices that are subject to specific federal requirements.²²⁶ The *Medtronic* decision, however, leaves undecided the question of whether the premarket approval or investigational device exemption processes impose device specific requirements. The decision will likely have the effect of preserving a preemption defense for manufacturers of medical devices obtaining premarket approval in at least some jurisdictions, notwithstanding the *Medtronic* plurality's conclusion that Congress did not intend for the MDA to preempt most common law claims.²²⁷ An

224. For example, in *Reeves v. AcroMed Corp.*, the Fifth Circuit Court of Appeals found that the MDA did not preempt an "unreasonably dangerous per se claim" against the manufacturer of a bone implant that arrived on the market through the premarket notification process. See 103 F.3d 442, 447 (5th Cir. 1997). Unreasonably dangerous per se claims are essentially similar to defective design claims. See *id.*

225. See *Medtronic*, 116 S. Ct. at 2258; *id.* at 2261 (Breyer, J., concurring).

226. See *Papike v. Tambrands Inc.*, 107 F.3d 737, 740-42 (9th Cir.) (finding that FDA regulation mandating that tampon labels contain specific substantive information preempts tort claims based on failure to warn), *cert. denied*, 118 S. Ct. 166 (1997).

227. See *Medtronic*, 116 S. Ct. at 2252 (plurality opinion); see also *King v. Collagen Corp.*, 983 F.2d 1130, 1135-36 (1st Cir. 1993) (finding that the premarket approval process imposes requirements on a device). The plurality's conclusion that Congress did not intend the MDA to preempt most state law tort claims probably will not prevent courts from finding preemption in future medical device cases because the precedential authority of a case is limited to its *ratio decidendi*. See Mark Alan Thurmon, Note, *When the Court Divides: Reconsidering the Precedential Value of Supreme Court Plurality Decisions*, 42 DUKE L.J. 419, 423 (1992). The *ratio decidendi* of a case is comprised of only the "conclusions necessary to reach the result in that case." *Id.* In order to determine whether a conclusion is part of the *ratio decidendi* of a case, an effective test is to reverse the meaning of the conclusion and then see whether the result of the case would remain the same. See *id.* at 423-24. If the result of the case does not change when the meaning of a conclusion is reversed, then the conclusion is not part of the *ratio decidendi* of the case and is merely dicta. See *id.* at 424. The Wambugh test for finding the *ratio decidendi* of a case was refined by Professor A.L. Goodhart, who emphasized the significance of determining what facts a judge believed to be material to the outcome of a case. See *id.* (citing Arthur L. Goodhart, *Determining the Ratio Decidendi of a Case*, 40 YALE L.J. 161 (1930)). The prevailing approach for determining the *ratio decidendi* of a case is that "[t]he *ratio decidendi* of a case is any rule of law expressly or impliedly treated by the judge as a necessary step in reaching his conclusion, having regard to the line of reasoning adopted by him." *Id.* at 426 (quoting RUPERT CROSS & J.W. HARRIS, *PRECEDENT IN ENGLISH LAW* 72 (4th ed. 1991)).

examination of the plurality opinion in *Medtronic* shows that significant parts were mere dicta.²²⁸ In Part IV of the opinion, a part in which Justice Breyer did not join, the plurality concluded that § 360k was not intended to preempt most common law duties enforced by state damages actions.²²⁹ The plurality arrived at this conclusion after finding that the Court's reasoning in *Cipollone* was not dispositive of the preemptive scope of the MDA because of differences in the statutes at issue.²³⁰ The plurality also based this conclusion on its finding that the legislative history of the MDA offered no indication that Congress intended the MDA to preempt most state tort claims.²³¹ Additionally, in Part VI of its opinion, the plurality concluded that future instances of preemption under the MDA would be few because it would be rare for a substantive requirement for a specific device to result from a common law claim.²³² All of the above conclusions, however, were unnecessary for the Court to hold that the MDA did not preempt Ms. Lohr's claims because the plurality had determined that no federal requirements were applicable to Medtronic's pacemaker lead that would have preempted Ms. Lohr's claims anyway.²³³

A comparison of the plurality and concurring opinions of *Medtronic* exposes two areas of agreement on matters leading to the outcome of the case.²³⁴ Both the plurality and concurring opinions agree that the MDA do not preempt common law claims unless there is a federal regulation specifically applicable to the device,²³⁵ and that the premarket notification process does not impose device specific regulations.²³⁶ Both opinions

228. See *supra* note 227 (discussing the limited precedential authority of Supreme Court plurality decisions).

229. See *Medtronic*, 116 S. Ct. at 2253 (plurality opinion).

230. See *id.* at 2252; see also *supra* note 181 (discussing the plurality's differentiation between the narrow scope of preemption clause in the Public Health Cigarette Smoking Act of 1969 at issue in *Cipollone* and the broad scope of § 360k at issue in *Medtronic*).

231. See *Medtronic*, 116 S. Ct. at 2252-53 (plurality opinion).

232. See *id.* at 2259.

233. See *id.* at 2257. It is clear that these conclusions are not part of the plurality's *ratio decidendi* because, Justice Breyer, while rejecting these conclusions in his concurring opinion, nonetheless arrived at the same outcome. See *id.* at 2261-62 (Breyer, J., concurring in part and concurring in the judgment).

234. These areas of agreement are critical to determining the *ratio decidendi*, and hence, the precedential authority of the opinion. Determining the *ratio decidendi* of a plurality decision is a two-step process. See Thurmon, *supra* note 227, at 426. First, the *ratio decidendi* for the main opinion and each concurring opinion must be determined. See *id.* Second, the *rationes decidendi* of all the opinions must be compared to determine the extent of agreement among them. See *id.*

235. See *Medtronic*, 116 S. Ct. at 2256-57, 2260-61.

236. See *id.* at 2258; *id.* at 2261 (Breyer, J., concurring in part and concurring in the

also agree that common law claims alleging violations of FDA requirements do not impose additional or different requirements on a device.²³⁷ Accordingly, the precedential value of *Medtronic* is limited to these areas.²³⁸

Five Justices²³⁹ agreed that state tort actions impose requirements, just like positive enactments of state law, and are subject to preemption by the MDA in some instances.²⁴⁰ Unlike the premarket notification process, which imposes no requirements on the design of a device and only general requirements on the manufacturing and labeling of a device, some courts have found that the premarket approval process imposes many specific requirements on the design, labeling, and manufacture of a device.²⁴¹ The premarket approval process requires applicants to submit design plans,²⁴² proposed labeling content,²⁴³ and manufacturing meth-

judgment).

237. See *id.* at 2255 (plurality opinion); *id.* at 2259 (Breyer, J., concurring in part and concurring in the judgment).

238. See *supra* note 227 (discussing the precedential authority of a decision); *supra* note 234 (discussing the methodology for determining the *ratio decidendi* of plurality opinions).

239. The five Justices were Breyer, Thomas, Scalia, O'Connor, and Chief Justice Rehnquist. See *Medtronic*, 116 S. Ct. at 2259 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2262 (O'Connor, J., dissenting).

240. See *id.* at 2259 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2262 (O'Connor, J., dissenting).

241. See *King v. Collagen Corp.*, 983 F.2d 1130, 1135-36 (1st Cir. 1993). *But see Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996) (stating that "[t]he fact that the premarket approval process involves specific requirements must not be confused with the premarket approval requirement itself acting as a specific requirement" (internal citation omitted)). In one post-*Medtronic* case, the New York Supreme Court, Appellate Division considered how the United States Supreme Court's reasoning in *Medtronic* extends to cases involving extended wear contact lenses that had undergone premarket approval review. See *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 19-20 (N.Y. App. Div. 1997). The court conceded that the premarket approval review process was much more rigorous than the premarket notification process, but found that it did not impose specific requirements on the device at issue. See *id.* at 20. The court reasoned that the premarket approval process was applicable to all medical devices subject to the process, with no requirements being specifically applicable to contact lenses. See *id.* Additionally, the court noted that the Supreme Court granted certiorari, vacated the judgment, and remanded for consideration in light of *Medtronic*, a Seventh Circuit decision finding that § 360k preempted a plaintiff's tort claims because the device in question had undergone premarket review. See *id.* at 21 (citing *Mitchell v. Collagen Corp.*, 116 S. Ct. 2576 (1996)).

242. See 21 U.S.C. § 360e(c)(1)(B) (1994) (requiring applicants for premarket approval to submit "a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device").

243. See *id.* § 360e(c)(1)(F) (requiring the applicant to submit a sample of the proposed labeling of the device).

ods²⁴⁴ for the device to the FDA for approval. Courts that deem the premarket approval process imposes requirements on a device, due to the comprehensiveness and specificity of the process, will find preemption of tort claims against medical device manufacturers.²⁴⁵

*B. A Preemption Defense Will Likely Remain Available for
Manufacturers of Other Federally Regulated Products*

The Supreme Court's decision in *Medtronic, Inc. v. Lohr*²⁴⁶ is of little precedential value outside the medical device field.²⁴⁷ A majority of the Court did not subscribe to the plurality's reasoning to the extent that the plurality sought to limit the impact of *Cipollone* and return to the virtually conclusive presumption against preemption of state tort claims evident in *Silkwood*. The Court's decision in *Medtronic*, however, does provide an indication of how the Justices are likely to divide when the Court hears future cases involving preemption of tort claims. Two federal statutes that include preemption clauses similar to that of the MDA²⁴⁸ are the National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA)²⁴⁹ and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).²⁵⁰

The NTMVSA prohibits states from imposing motor vehicle safety standards that differ from the federal standards promulgated under the

244. See *id.* § 360e(c)(1)(C) (requiring applicants to submit "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, [the] device").

245. Similarly, courts that deem the Investigational Device Exemption application approval process to impose specific requirements on devices will continue to find preemption of tort claims. See generally *supra* note 20 (discussing the IDE). For example, the Sixth Circuit Court of Appeals, after *Medtronic*, found that § 360k preempted all of the plaintiff's tort claims against the manufacturer of a device that had come to the market through an IDE. See *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1098-1101 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998).

246. 116 S. Ct. 2240 (1996).

247. See *supra* note 227 and accompanying text (discussing the precedential authority of the *Medtronic* plurality opinion); see also *Verb v. Motorola, Inc.*, 672 N.E.2d 1287 (Ill. App. Ct. 1996). In *Verb*, the Appellate Court of Illinois rejected plaintiffs' argument that *Medtronic* required a finding that the Electronic Product Radiation Control Act did not preempt tort claims based on misrepresentation and breach of warranty. See *id.* at 1293. The court reasoned, in part, that *Medtronic* was inapplicable because the *Medtronic* Court was interpreting a different statute. See *id.* at 1294.

248. 21 U.S.C. § 360k (1994).

249. Pub. L. No. 89-563, 80 Stat. 718 (1966). In 1994, Congress enacted a revised traffic safety statute that made no substantive changes to the NTMVSA. See Pub. L. No. 103-272, 108 Stat. 745 (1994) (codified at 49 U.S.C. §§ 30101-30169 (1994)).

250. Pub. L. No. 125-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (1994)).

Act.²⁵¹ Automobile manufacturers have successfully argued that the NTMVSA preempts common law claims alleging that a vehicle is defectively designed because it does not have an airbag.²⁵² Essential to the success of the manufacturers' preemption defense was the courts' treatment of the duties arising out of common law claims as state-imposed standards.²⁵³ After *Medtronic*,²⁵⁴ where five Justices agreed that common

251. See 42 U.S.C. § 30103(b) (1994). The NTMVSA also included a savings clause that provides that compliance with federal standards issued under the Act does not exempt a party from any common law liability. See 42 U.S.C. § 30103(e). Courts, however, often find preemption of design defect and negligent design claims against automobile manufacturers using an implied conflict preemption analysis. See, e.g., *Montag v. Honda Motor Co.*, 75 F.3d 1414, 1417 (10th Cir.), *cert. denied*, 117 S. Ct. 61 (1996); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122-23 (3rd Cir. 1990); *Wood v. General Motors Corp.*, 865 F.2d 395, 402 (1st Cir. 1988).

252. See *supra* note 251 (listing cases finding preemption of claims against automobile manufacturers). Federal Motor Vehicle Safety Standard No. 208 requires automobile manufacturers to either install airbags, shoulder-and-lap belts, or another passive protection systems. See 49 C.F.R. § 571.208 (1996). Automobile manufacturers have raised three different arguments in support of preemption of tort claims alleging that cars manufactured without airbags were negligently or defectively designed. See Ralph Nader & Joseph A. Page, *Automobile-Design Liability and Compliance with Federal Standards*, 64 GEO. WASH. L. REV. 415, 436 (1996). First, automobile manufacturers have argued that the Traffic Safety Act, on its face, precludes plaintiffs from "claiming that any aspect of a vehicle's design was defective" when the design complies with regulations promulgated by the National Highway Traffic Safety Administration (NHTSA) under the Act. See *id.*; see also *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1118-19 (3d Cir. 1990); *Taylor v. General Motors Corp.*, 875 F.2d 816, 823 (11th Cir. 1989). Second, manufacturers have argued that the Traffic Safety Act impliedly preempts such claims when a manufacturer can demonstrate compliance with federal regulations. See Nader & Page, *supra*, at 436; see also *Pokorny*, 902 F.2d at 1118-19. Third, manufacturers have argued that the Act impliedly preempts such claims because Federal Motor Vehicle Safety Standard No. 208 provides automobile manufacturers with the option of installing passive protection systems other than airbags and that allowing tort damage awards for failing to opt for airbags would frustrate congressional intent. See Nader & Page, *supra*, at 436; see also *Pokorny*, 902 F.2d at 1119; *Taylor*, 875 F.2d at 827.

Due to the uncertainty over the preemptive effect of the NTMVSA, some courts have reached a decision on the merits as to whether an automobile that is not equipped with an airbag is defectively designed. See Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1142 n.49 (1994). Compare *Taylor*, 875 F.2d at 821 (holding that a claim based on an automobile manufacturer's failure to equip an automobile with an airbag is viable under Florida law) and *Staggs v. Chrysler Corp.*, 678 F. Supp. 270, 273 (N.D. Ga. 1987) (holding same under Georgia law), with *Wilson v. Ford Motor Co.*, 656 F.2d 960, 960 (4th Cir. 1981) (*per curiam*) (finding an automobile manufacturer not liable for design attributes that aggravated, rather than caused an injury).

253. See *Wood*, 865 F.2d at 402. Courts finding both implied and express preemption under the NTMVSA have shared this understanding of the common law duties arising from tort claims. See *Staggs*, 678 F. Supp. at 272-73 (implied preemption); *Vanover v. Ford Motor Co.*, 632 F. Supp. 1095, 1096-97 (E.D. Mo. 1986) (express preemption).

254. 116 S. Ct. 2240 (1996).

law damage awards are state-imposed requirements, the courts will probably continue to find preemption of tort claims under the NTMVSA.²⁵⁵

Similarly, FIFRA, which requires an EPA-approved label on chemicals regulated by the Act, contains a clause prohibiting state labeling requirements different from or in addition to the approved label.²⁵⁶ Following the Supreme Court's *Cipollone*²⁵⁷ decision, courts concluded that FIFRA preempts improper labeling claims against manufacturers who have complied with EPA regulations.²⁵⁸ Again, essential to the success of chemical manufacturers' preemption defense was the treatment of common law claims as state-imposed requirements.²⁵⁹ Because a majority of

255. For example, in *Harris v. Ford Motor Co.*, the Ninth Circuit found that the NTMVSA preempted a state-law tort claim alleging that an automobile was designed defectively because it did not have an airbag. See 110 F.3d 1410, 1414 (9th Cir. 1997). The court found that Standard 208 was precisely the type of specific requirement that would preempt a common law claim under *Medtronic*. See *id.* at 1414 (citing *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2258 (1996)).

256. See 7 U.S.C. § 136v(b) (1994) (providing that a "[s]tate shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter").

257. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

258. See *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995) (breach of express warranty claim); *Taylor AG Ind. v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995) (inadequate warning claim). FIFRA provides that before a pesticide may be registered with the EPA, the labeling must comply with FIFRA requirements. See 7 U.S.C. § 136a(c)(5)(B) (1994).

259. See *Welchert*, 59 F.3d at 73. In *Welchert*, for example, the Eighth Circuit Court of Appeals found that state court consideration of an EPA approved label would constitute an additional requirement and that FIFRA, therefore, preempted the plaintiff's claims. See *id.* In *Welchert*, the plaintiffs, the Welchert family, were commercial farmers. See *id.* at 70. In May 1989, property leased by the Welcherts was treated with a herbicide manufactured by defendant, American Cyanamid. See *id.* According to the herbicide's label, vegetables could be planted safely on herbicide treated land within 18 months after an application of the chemical. See *id.* See generally 7 U.S.C. § 136(u) (1994) (defining pesticides under FIFRA to include herbicides). Relying on the information stated on the herbicide's label, the Welcherts planted crops on the land in 1991. See *Welchert*, 59 F.3d at 70. When the crops failed to grow, the Welcherts filed suit against Cyanamid seeking to recover for the damage to their crops allegedly caused by the herbicide. See *id.* The complaint included claims of breach of express and implied warranties. See *id.* The district court held that FIFRA preempted the implied warranty claims but did not preempt the express warranty claims. See *id.*

The issue on appeal was whether FIFRA preempted the Welcherts' express warranty claim. See *id.* at 72. Relying on *Cipollone*, the Eighth Circuit understood common law claims to constitute state-imposed requirements. See *id.* at 71, 73. In *Cipollone*, the Supreme Court held that the Public Health Cigarette Smoking Act of 1969, which contained preemption language similar to that in FIFRA, did not preempt breach of express warranty claims because an express warranty represents a requirement voluntarily undertaken by the warrantor, rather than one imposed by state law. See 505 U.S. at 525 (plurality

the Court in *Medtronic*²⁶⁰ agreed that common law damage awards constitute state-imposed requirements, courts will continue to find preemption under FIFRA.²⁶¹

C. A Majority of the Supreme Court Ignored Congressional Intent and the Historical Presumption Against Preemption of State Tort Claims

With its decision in *Medtronic*, the Supreme Court correctly preserved Ms. Lohr's common law claims.²⁶² The reasoning adopted by a majority of the Court, however, failed to apply the fundamental principles of preemption analysis: that the touchstone of any preemption analysis is the intent of Congress,²⁶³ and that the intent of Congress to supersede the historic police powers of the states must be clear and manifest.²⁶⁴ The Court should have based its decision on the reasoning of *Silkwood* that: (1) the presumption against preemption in areas traditionally subject to the police powers of the state forces the conclusion that a statute does not preempt state common law claims without any mention of such claims and without the creation of an alternative remedy; and (2) common law damages are an insufficiently direct form of regulation to trigger conflict preemption.²⁶⁵

Congress undoubtedly was aware of the significance of tort law to both manufacturers and consumers when it enacted the MDA, as evidenced by House reports discussing the extensive litigation surrounding deaths and injuries allegedly caused by defective medical devices.²⁶⁶ Justice Breyer and the dissenting Justices therefore unreasonably concluded that Congress's clear and manifest intent was to grant the medical device industry immunity from tort claims when the MDA did not address such

opinion). The Eighth Circuit distinguished the express warranty claims arising from EPA required labels from the claims in *Cipollone*, explaining that the voluntary nature of express warranties is missing when the EPA dictates their content. *See Welchert*, 59 F.3d at 72 (citing *Lowe v. Sporicidin Int'l*, 47 F.3d 124, 129 (4th Cir. 1995)). Accordingly, the court found that FIFRA preempted the Welcherts' express warranty claims because the claims were based solely on EPA-mandated labeling. *See id.* at 73.

260. 116 S. Ct. 2240 (1996).

261. *See Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2259 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2262 (O'Connor, J., dissenting).

262. *See id.* at 2259 (Breyer, J., concurring in part and concurring in the judgment).

263. *See id.* at 2250.

264. *See id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

265. *See Silkwood v. Kerr-McGee*, 464 U.S. 238, 251 (1984); *see also supra* Part I.A (discussing *Silkwood*).

266. *See H.R. REP. NO. 94-853*, at 8 (1976). At the time Congress considered the Medical Device Amendments, "the [Dalkon] Shield had been linked to sixteen deaths and twenty-five miscarriages," resulting in more than 500 lawsuits seeking aggregate punitive and compensatory damages of more than \$400 million. *Id.*

claims and did not create an alternative remedy for injured plaintiffs.²⁶⁷ In *Medtronic*, Justice O'Connor, in support of her conclusion that common law damage awards are a form of direct state regulation, cited the Supreme Court's decision in *San Diego Building Trades Council v. Garmon*.²⁶⁸ The *Garmon* decision, however, involved a situation in which Congress determined that the National Labor Relations Board should be the plaintiff's exclusive source of remedy,²⁶⁹ unlike the MDA where Congress did not provide plaintiffs with any federal remedy.²⁷⁰ Additionally, the *Medtronic* Court ignored the fact that damages awards do not have the same direct regulatory effect on a manufacturer as do administrative and legislative regulations, and, therefore, should not be considered state-imposed requirements.²⁷¹ Faced with an administrative or legislative regulation, a manufacturer has no choice but to comply with the

267. Justice Breyer's and the dissenting justices' conclusion is particularly unreasonable where Congress is enacting legislation intended to protect the public from unsafe or ineffective medical devices. At the time Congress passed the MDA, most courts viewed a manufacturer's compliance with federal safety standards as merely constituting "some evidence of due care," rather than being dispositive of the issue, or preemptive. See Adler & Mann, *supra* note 14, at 940 n.184; see also *Raymond v. Riegel Textile Corp.*, 484 F.2d 1025, 1027-28 (1st Cir. 1973); *LaGorga v. Kroger Co.*, 275 F. Supp. 373, 378 (W.D. Pa. 1967); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1085-86 (D.C. Ct. App. 1976); *Jonescue v. Jewel Home Shopping Serv.*, 306 N.E. 2d 312, 316 (Ill. App. Ct. 1973); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387, 394 (Tex. Civ. App. 1968).

268. See *Medtronic*, 116 S. Ct. at 2262 (O'Connor, J., dissenting) (quoting *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959), for the proposition that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief").

269. See *Garmon*, 359 U.S. at 247; see also Barbara L. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 BUFF. L. REV. 181, 189-90 (1991) (noting that the Court's decision in *Garmon* "does not necessarily affect other cases where the normal presumption against preemption applies").

270. See *Medtronic*, 116 S. Ct. at 2251 (plurality opinion). In Part IV of the plurality opinion of *Medtronic*, which only four Justices joined, Justice Stevens noted that the MDA did not create any rights of action for injured consumers. See *id.* Addressing *Medtronic's* argument that the MDA preempted any common law claims against a manufacturer of medical devices brought by injured consumers, Justice Stevens found the lack of any federal cause of action to be evidence to the contrary. See *id.*

271. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 536-37 (1992) (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) ("The level of choice that a defendant retains in shaping its own behavior distinguishes the indirect regulatory effect of the common law from positive enactments [of law]"). See generally Carl T. Bogus, *War on the Common Law: The Struggle at the Center of Products Liability*, 60 MO. L. REV. 1, 69-70 (1995). Bogus notes that a manufacturer is free to continue selling his product after a finding of liability, and that while the manufacturer may be forced to raise the price of that product to cover the costs of the liability, it is simply a result of market forces if the manufacturer is thereby driven from the market. See *id.* at 69.

regulation or cease doing business.²⁷² Faced with a damages award, a manufacturer may choose to pay the award, consider the award a cost of doing business, and take its chances with another jury in the future.²⁷³ Additionally, the Court failed to consider that the underlying goal of tort awards, particularly those involving compensatory damages, is to compensate victims, not to regulate conduct.²⁷⁴ As a result of the Supreme Court's flawed reasoning in *Medtronic*, courts will continue to find preemption of state tort claims contrary to congressional intent.²⁷⁵

V. CONCLUSION

Medtronic v. Lohr indicates that a majority of the Supreme Court does not adhere to the historical presumption against preemption of state tort claims. Only four Justices sought to return to the pre-*Cipollone* era, where federal statutes enacted to protect health and safety did not forestall injured plaintiffs' tort claims against regulated defendants. By focusing on the FDA's interpretation of the MDA's preemptive scope and the issue of device specificity, instead of focusing on the purpose of the statute and the nature of common law damages, the Court ensured that plaintiffs injured by premarket approval-exempt devices may seek com-

272. See *Cipollone*, 505 U.S. at 536-37 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part).

273. See *id.* at 536.

274. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 263-64 (1984) (Blackmun, J., dissenting in part).

275. For example, Congress did not intend FIFRA's prohibition on additional or different state requirements relating to the labeling of chemicals to include common law duties arising out of state tort claims. Shortly after the Supreme Court decided *Silkwood*, the United States Court of Appeals for the District of Columbia, in *Ferebee v. Chevron Chemical Co.*, held that FIFRA did not preempt a failure to warn claim against the manufacturer of a FIFRA regulated chemical manufacturer. See 736 F.2d 1529, 1543 (D.C. Cir. 1984); see also Corboy & Smith, *supra* note 7, at 470 (asserting that Congress's lack of response to *Ferebee* was evidence of a lack of intent that FIFRA preempt tort claims). The complaint in *Ferebee* alleged that a chemical manufacturer's EPA-approved label failed to warn of the dangers of prolonged contact with the skin. See 736 F.2d at 1531-32. The court reasoned that the damages award did not require Chevron to change its label or stop selling the chemical in Maryland; rather, the award served to warn Chevron that it may have to compensate victims if it continued to sell the chemical in that state. See *id.* at 1541. Additionally, the court noted that common law claims against FIFRA-regulated manufacturers may serve to further the goals of FIFRA because such claims provide an additional incentive for manufacturers to improve their labeling. See *id.* at 1541-42.

In 1988, Congress extensively revised FIFRA. See H.R. REP. NO. 100-939 (1988). At that time, *Ferebee* was the only federal appellate opinion analyzing the preemption of tort claims by FIFRA. See Corboy & Smith, *supra* note 7, at 470-71 (asserting that Congress's lack of response to *Ferebee* indicated that Congress did not intend FIFRA to preempt state tort claims). Congress, however, made no substantive changes to the preemption clause in FIFRA and did not indicate any disagreement with *Ferebee*. See *id.*

pensation. The Court also fostered the possibility that people injured by federally regulated actors will find their claims preempted by statutes enacted to promote safety.